OUTCOMES IN PEOPLE WITH ALCOHOL DEPENDENCE SYNDROME TREATED IN A TERTIARY CARE HOSPITAL
A 3 MONTH PROSPECTIVE COHORT STUDY

Dissertation submitted to

The Tamil Nadu Dr.MGR Medical University

in part fulfillment of the requirement for

MD Branch XVIII Psychiatry Final Examination to be held in April 2017

CERTIFICATE

This is to certify that the dissertation titled "OUTCOMES IN PEOPLE WITH ALCOHOL DEPENDENCE SYNDROME TREATED IN A TERTIARY CARE HOSPITAL – A 3 MONTH PROSPECTIVE COHORT STUDY" is a bonafide work of Dr. Preeti Mathew in partial fulfillment of the requirements for the MD-Psychiatry (Final) examination of the TN Dr.MGR Medical University to be conducted in April 2017.

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DECLARATION

I hereby declare that this dissertation titled "OUTCOMES IN PEOPLE WITH ALCOHOL DEPENDENCE SYNDROME TREATED IN a TERTIARY CARE HOSPITAL – A 3 MONTH PROSPECTIVE COHORT STUDY" was prepared by me in partial fulfillment of the regulations for the award of the degree of MD-Psychiatry of the TN Dr.MGR Medical University, Chennai.

Signature:

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I thank all my colleagues, friends and professors for their help, support and constant concern.

I thank the Principal and the management of Christian Medical College, Vellore for permitting me to undertake this study.

Dr. Preeti Mathew

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Outcomes in people with alcohol dependence
syndrome treated in a tertiary care psychiatric hospital - A 3 month follow up study
Dr.Preeti Mathew, P.G.Registrar, Department of Psychiatry, Dr. Deepa Braganza, Psychiatry, Dr. Prince R, Psychiatry

Ref: IRB Min No: 9561 [OBSERVE] dated 05.08.2015

Dear Dr. Preethi Mathew,,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Outcomes in people with alcohol dependence syndrome treated in a tertiary care psychiatric hospital - A 3 month follow up study" on August 05th 2015.

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
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The Committee raised the following documents

1. IRB Application format
2. Initial and second Assessment Proforma
3. Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-Ar)
4. Proforma
5. Rotter's Locus of Control Scale
6. SADD – short Alcohol Dependence Data Questionnaire (English and Tamil)
7. Information Sheet and Consent Form (English and Tamil)
8. Cvs of Drs. Deepa Braganza Preeti Mathew, Prince R,
9. No of documents 1 - 4

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on August 05th 2015 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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Dr. Anup Ramachandran	PhD	The Wellcome Trust Research Laboratory Gastrointestinal Sciences, CMC, Vellore	Internal, Basic Medical Scientist

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Outcomes in people with alcohol dependence syndrome treated in a tertiary care psychiatric hospital - A 3 month follow up study" on a monthly basis. Please send copies of this to the Research Office research@cmcvellore.ac.in

Fluid Grant Allocation:

A sum of 7,700/- INR (Rupees Seven Thousand Seven hundred only) will be granted for 12 months.

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
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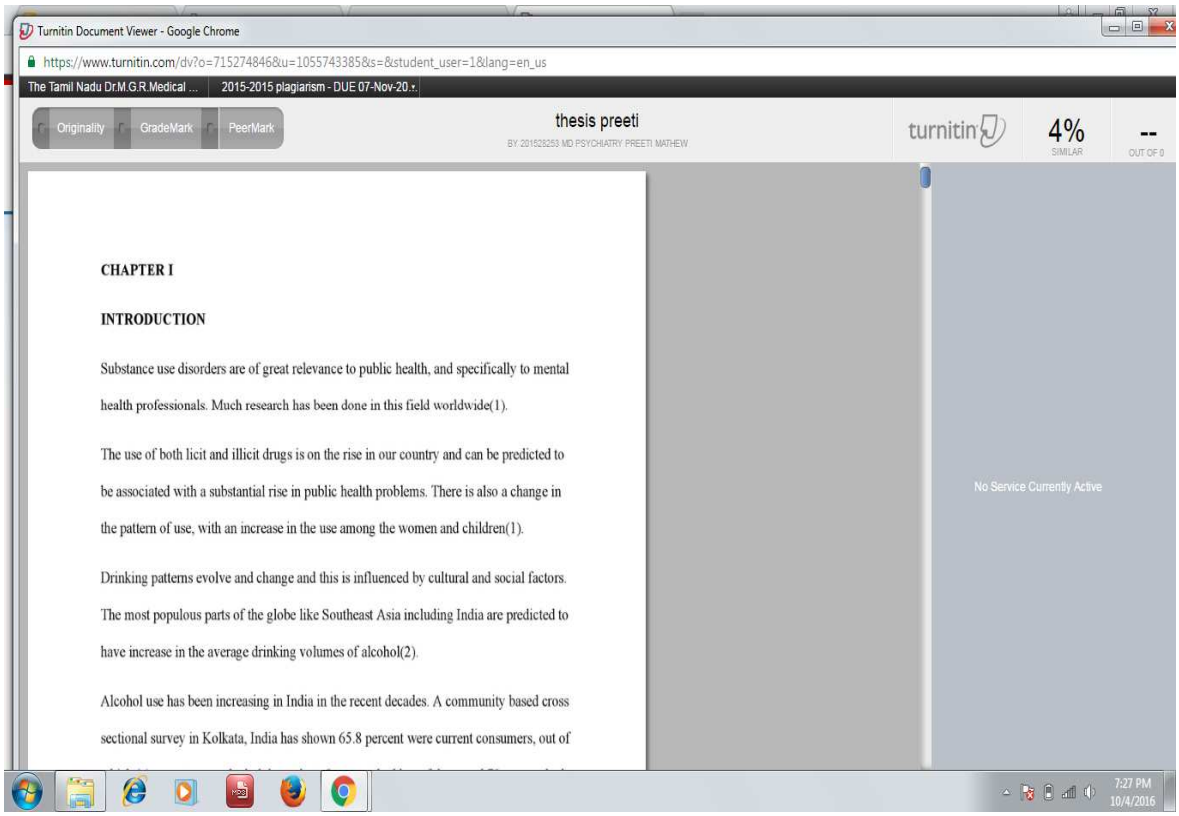
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CHAPTER I
INTRODUCTION
Substance use disorders are of great relevance to public health, and specifically to mental health professionals. Much research has been done in this field worldwide(1).
The use of both licit and illicit drugs is on the rise in our country and can be predicted to be associated with a substantial rise in public health problems. There is also a change in the pattern of use, with an increase in the use among the women and children(1).
Drinking patterns evolve and change and this is influenced by cultural and social factors. The most populous parts of the globe like Southeast Asia including India are predicted to have increase in the average drinking volumes of alcohol(2).
Alcohol use has been increasing in India in the recent decades. A community based cross sectional survey in Kolkata, India has shown 65.8 percent were current consumers, out of
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CHAPTER I

INTRODUCTION

Substance use disorders are of great relevance to public health, and specifically to mental health professionals. Much research has been done in this field worldwide(1).

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Alcohol use has been increasing in India in the recent decades. A community based cross sectional survey in Kolkata, India has shown 65.8 percent were current consumers, out of which 14 percent were alcohol dependent, 8 percent had harmful use and 78 percent had non-harmful use of alcohol. About 41 percent people drank alcohol in public and in the work place. Only 16 percent had concerns for alcohol use and 62 percent of those dependent had clinical signs of chronic alcohol use(3).

Studies have indicated that the negative outcome of alcohol use in India is related to younger age of onset, early development of dependence pattern, family history of

alcohol use, various psycho-social problems and less frequent follow up with health services(4).

Studies have also indicated that there are no difference in outcome in terms of economic status, marital status, religion, educational level, social support, associated mental or medical illness, type of treatment and in-patient treatment days(4).

The familial clustering of alcoholism leads to an early onset of drinking behavior, eventually causing serious problems due to alcohol misuse and poor response to treatment strategies(1).

In a follow up study done in India, it was seen that a longer duration of in-patient stay and higher income were related to a better outcome(5).

In the Indian context perceived social support seemed to be a detrimental factor in maintenance of abstinence(5).

In a naturalistic uncontrolled follow up study done in Pondicherry, pre-treatment variables were not associated with either favorable or unfavorable outcome. However , the duration of Disulfiram use was found to be associated with a favorable outcome(6).

The combination of family therapy along with pharmacological intervention has been shown to have a good outcome with reduction in relapse rate and prolongation of the abstinence period(7).

Other studies have suggested that craving is a detrimental factor associated with any substance relapse. The frequency of craving is inversely proportional to the length of abstinence period(1).

However, in India, evidence from longitudinal studies evaluating alcohol use disorder course and outcome is sparse. Possible reasons for this include small sample size, short follow up periods, and restricted help seeking and treatment seeking behavior in alcoholic men .The patients who seek treatment for alcohol use do not get evidence based treatment and the effective treatment gap is huge compared to the ideal treatment(8).

Due to lack of such longitudinal studies related to course and outcome of alcohol use disorders, India does not have stable national policies for alcohol , despite alcohol being a major public health issue(8).

More research is needed in the area of alcohol use in India focusing at identifying factors associated with positive and negative outcomes.

The present study aimed at examining factors associated with complete abstinence after a follow up period of 3 months. The pre-treatment and treatment variables were collected in a prospective manner and an attempt was made to find the associations of these variables with the outcome of complete abstinence.

CHAPTER II

Review of Literature

2.1 Concept of Alcoholism and its treatment

One of the earliest mentions of alcohol is in the late Stone Age, with the observation of natural fermentation of honey or fruit. Fermented barley, in the form of beer, was first introduced in the ancient Egyptian and Mesopotamian culture(9).

The first production of wine, from grape juice, took place in 6000 B.C in Armenia(9).

Drinking culture and attitude varies worldwide. Seasonal variation, socio-political factors and ecological diversities influence drinking patterns in the European regions(10).

The Roman culture practices drinking wine with the meals. The Germanic culture prefers “malt liquor” during feasts. Beer is the traditional beverage of the northern European regions and wine is the traditional beverage of southern Europe. In southern Europe viticulture is practiced widely(10).

Northern Europe practices heavy drinking patterns, leading to problems related to public drunkenness due to which various health policies and legal age for alcohol consumption has been established in this part of the world(10).

The European countries witness a seasonal variation in drinking pattern. Studies have shown that per capita alcohol consumption increases in winter, during dark compared tolight days. During winters many individuals suffer from depression, which possibly leads to an increase in alcohol consumption(10).

The modern drinking pattern in the West arises from the southern European culture of consumption of wine during meals and is also influenced by Christianity(10).

The attitudes related to alcohol use have also been changing in India as it is worldwide. Alcohol has been a much debated and ambivalent issue in the Indian subcontinent. These ever changing concepts, reflect the changes in the cultural, religious and political attitudes(11).

The Vedas, the Chakara and the Susrata, highlight the use of moderate alcohol use. Whereas, Buddhism and the Jainism propagated the anti-alcohol doctrine(11).

The Mughal era, showed a widespread use of alcohol among the people, in spite of total opposition to it in Islamic teaching(11).

British colonial rule influenced alcohol use immensely, with an increased use in the warrior (Kshatriyas) communities but complete prohibition in the Brahmin communities. These ambiguities eventually led to heavy, hazardous and high risk use in certain section of people in the Indian society(11).

Earlier, problem drinking was considered as a “bad habit” equivalent to “sin”. This morality concept influenced the approaches used to tackle this so called “bad habit”.

The strategies, which were used initially to address the alcohol problem, included the traditional moral educational approach(12).

Thus the initial literature for alcohol use treatment focused more on the spiritual and moral realms reflected in the conceptual framework of Alcoholics Anonymous(13).

The disease model for alcoholism has appeared over the last fifty years. This model evolved from incorporating the informal principles from Alcoholic Anonymous with the biological concept derived from evidence for heritability and genetic determinants(14).This model proposes a medical or biological approach to substance use disorders, which considers substance use disorder, equivalent to a chronic medical illness(12).

It suggests that just as chronic medical illness has a relapsing course, which requires lifelong medication to keep the disease under control, so is the case with substance use disorders. This concept of substance use disorder suggests that substance abuse too has a relapsing chronic course requiring regular clinical care and monitoring. The treatment approach includes medication along with holistic care in the form of behavioral, social and family therapies(12).

It offers a new understanding for addiction care, where relapse is considered as an inevitable, natural and expectable part of the therapy and not a marker for treatment failure. Thus the early detection of relapse and intensifying the pace of treatment becomes an integral part of therapy through continued care for a better outcome(12).

It has helped in formulating better treatment modalities, health policies and research strategies(12).

2.2 Extent of the problem

2.3 The Indian scenario

There are various cultures, religion and geographical boundaries in India. The attitude towards alcohol and the pattern of use are influenced by these variations. There exists, a significant variation in regional and national prevalence for any substance including alcohol(1). However, the per capita consumption of alcohol has increased by 55 % over the last 20 years(15).

In a vast country like India, most studies on the epidemiology of alcohol use disorders have been regional. Hence the results vary according to the population surveyed. A meta-analysis by Reddy and Chandrashekhar (1998) concluded an overall substance use prevalence of 6.9/1000 for India. The urban prevalence was found to be 5.8/1000 and the rural prevalence was found to be 7.3 /1000 (1).

The rate of substance use in males and females in India was found to be 11.9 and 1.7 percent respectively(1).

Hazardous alcohol use was found to be 14.2 percent in the rural South Indian population. About 17.6 percent patients admitted in a tertiary care hospital in South India were found to have hazardous alcohol use(1).

The annual incidence of nondependent and dependent alcohol use in a cohort study done in Delhi, was found to be 3 and 2 per 1000 men, respectively(1).

In the national household survey of drug use, alcohol was found to be the primary substance of use followed by tobacco, cannabis and opioids. Alcohol amounted to about 21.4 % of the total substance used in India. Alcohol dependence was found to be 17-26 % among the alcohol users. There were regional variation in alcohol use prevalence with lowest being Gujarat of about 7 % and highest being northeastern Andhra Pradesh with about 75 %(1).

There is an increase in the pattern of alcohol among males in India, according to the National Family Health Survey. The Drug Abuse Monitoring system found alcohol to be the major substance of abuse at 43.9%(1).

A Rapid Situation Assessment by UNODC in 2002, showed alcohol to be the second major substance used (33 %) next to cannabis (40%). About 80 % of drug users concomitantly used alcohol with other drugs(1).

The GENACIS study covering five districts of Karnataka, brought to light the issues pertaining to female alcoholism. The study showed that at least 5.9 % women drank alcohol at least once in the last 12 months(1).

A survey of 1865 women, in India had shown that about 87 percent of women who had substance abuse had concomitantly used alcohol(1).

There is also a rise in alcohol use in the medical professionals. A youth survey by WHO (1982) showed that about 22.7 % male medical professionals indulged in high risk alcohol use atleast once in a month(1).

The most common substance of abuse by children is tobacco which becomes the gateway drug for various other substances. A study done in Andaman islands, showed that age of onset of alcohol being late childhood and early adolescence, progressing to increased alcohol consumption in adulthood(1).

A study in Goa showed a prevalence of hazardous alcohol use of about 211/1000 population(1).

Alcohol dependence is a major problem in the psychiatry department of the armed forces where alcohol been mainly used in the context of stressful life events, neuroticism, extroversion, anxiety and depression(1).

There is a high life time prevalence of co-morbidity with alcohol use ranging to about 60%. Depression, cluster B personality and phobia being most commonly associated. Early onset of alcohol use is associated with childhood ADHD(1).

The literature review in Indian context suggests that in the year 2005, the estimated numbers of alcohol users were 62.5 million and 17 % of them (10.6 million) were dependent users. Alcohol related problems amounted to about 20–30% of hospital the admissions(16).

India is witnessing a high rate of social, physical and economic consequences due to alcohol use disorders. Despite the increasing devastation caused, there is a huge treatment gap for alcohol use disorder in our country. This gap is partly due to the stigma associated with the behavior and the reluctance to seek help. The lack of public health services and difficulty in accessing the private health sector are also contributing to the suboptimal treatment seeking behavior in the Indian population(15).Community based studies focusing on various treatment modalities for alcohol use disorder in India is lacking (15).

2.4 Treatment

The treatment for alcoholism has changed remarkably in the past 50 years. There have been significant strides in both the non-pharmacological and pharmacological treatment modalities(17).

The trajectory of development of alcohol dependence varies from individual to individual. There are multiple factors influencing individual alcoholism which includes individual related factors, environmental factors and contextual factors, all of which get colored by the political, cultural and social resources(12).

The current treatment strategies do not just treat the dependent person but also address a variety of psycho-social and family issues related to the patient(17).

The treatment of alcoholism is a comprehensive endeavor which includes the pharmacological management starting from targeting the withdrawal symptoms to

managing relapse. Social interventions, psychotherapy, and management of co-morbid physical and psychiatric condition are seen as essential complementary components of the treatment program(18).

Studies on treatment approaches have shown that the combination of pharmacological strategies for alcohol dependence, along with psychosocial and support therapy have a modest effectiveness in primary as well as tertiary medical settings(19).

The medications mainly target the neuro-physiological and genomic basis for alcohol use and the behavioral approaches address the habits which sustain the addiction(17). Studies have shown that treated individuals had higher rate of non-problem alcohol use at one year follow up period, when compared to untreated individuals , 40 % and 23 % respectively(20).

Maintaining abstinence from alcohol after detoxification has always been a challenge. It has been seen that 50 percent patient relapse within three months of detoxification(21).

A more intensive treatment strategy, keeping complete abstinence as a goal has shown more positive outcome when compared to less intensive treatment, which goals less than complete abstinence(22).

2.2 a. Pharmacological treatment

There are multiple pharmacological approaches used in the treatment of alcohol use disorders. Agents used have differing mechanisms of action and have varying effectiveness(1).

There is no specific pharmacological treatment strategy, which seems to be superior to the other. However, chemical aversion seems to be a favored approach(23).

Studies have shown better treatment outcome if the subjects have good adherence to medications. A combination of medication and behavior therapy to improve adherence have proven to have better outcome in non-adherent subjects(24).

Medication adherence along with a good working alliance with the therapist plays an important role in outcome(24).

Disulfiram is the oldest medication and the most inexpensive one among other medication(17).

In a study by Fuller et al, 1986, it was found that Disulfiram had a significant reduction in proportion of alcohol consumption days over a one year follow up study period, when compared with placebo or vitamin tablets(25).

Supervised Disulfiram, when given in a well-motivated individuals was found to be more effective in delaying the onset of relapse, when compared to naltrexone, acamprosate or topiramate alone(19).

Unsupervised Disulfiram did not have any advantage over placebo in terms of abstinence(19).

According to Fuller et al, Disulfiram can be given on an out-patient basis. Disulfiram replaces the reinforcing effect of alcohol use by immediate negative consequences and brings a break in the vicious circle of social and personal problem and further drinking(23).

Disulfiram has the best positive results by increasing treatment adherence when used with incentives, regular reminders from the patients relatives in adjunction with behavioral treatment and social support(25).

In Indian studies, it was found that Disulfiram is more effective in short term abstinence and treatment retention after detoxification. It does not help in preventing long term relapse. Disulfiram, assists in motivating individuals to maintain abstinence(25).

There are several theories regarding the role of opioids in alcohol use disorder. The Surfeit theory suggests that the individuals with genetic vulnerability to use alcohol have high resting levels of opioids which potentiates the effects of alcohol(26).

The opioid deficit theory suggests that low levels of endogenous opioids leads to alcohol dependence. In individuals with low levels of endogenous opioids alcohol causes hyperactivity of opiate receptors which ultimately enhances the reinforcing effect of alcohol consumption(26).

Naltrexone, an opioid antagonist, decreases excessive alcohol consumption by reducing the reward effects of drinking alcohol, reducing number of drinking days and reducing alcohol craving. (27)

A few studies have suggested the direct effect of alcohol on opioid receptors, opioid peptide synthesis and secretion of opioid peptides in experimental circumstances. The opioid antagonists such as naloxone and naltrexone have been shown to decrease alcohol consumption. Selective mu- or delta-receptor antagonists have also been shown to have a similar response. (28).

Clinical trials have shown that alcohol-dependent subjects who are treated with naltrexone in combination with psychological therapies have lower relapse with a decrease in the amount of alcohol consumed. The neurobiological mechanism proposed behind this action of naltrexone is the modifying effect of naltrexone in alcohol's reinforcing effect(26).

A meta-analysis of 19 controlled clinical trials of oral naltrexone, compared with placebo, for treatment of alcohol dependence, showed that a short term treatment of 12 weeks or less with naltrexone, resulted in significant improvement in relapse rate, with reduction in the number of drinking days, reduction in total amount of alcohol consumption and fewer number of drinks per drinking day, more days of abstinence, and longer times to relapse. Naltrexone possibly provides control and prevents lapses from becoming a full-blown relapse(29).

Depot naltrexone is the most recent form of naltrexone. This is given as a depot on a monthly basis and showed favorable results in terms of number of abstinent days when compared to placebo(19).

According to Garbutt et al there was a 25 % decrease in number of heavy drinking days over a period of six month in the naltrexone group when compared to the placebo group(19).

In a multi-centric trial of 315 subjects, with 158 receiving depot naltrexone and remaining subjects receiving placebo, monthly once for three months, it was found that the subjects on depot naltrexone had fewer drinking days and higher abstinence rate than the placebo group(18 % vs 10 %)(30).

Acamprosate is believed to maintain abstinence by ameliorating craving(31).

Multiple placebo comparison studies focusing on acamprosate have shown favorable changes in drinking outcomes with significantly greater percentage of abstinent days(19).

RCTs have shown that both acamprosate and naltrexone were equally effective when used individually, however their combination was found to be superior to acamprosate alone but not to naltrexone(19).

Studies have shown that acamprosate can clinically decrease the overall amount of alcohol intake , but does not alter the individuals propensity to relapse(32).

Oral Acamprosate of 1.3 to 2 gram per day given in three divided doses for 3 to 12 months was found to be more effective when compared to placebo in terms of relapse rates, abstinence rates and duration of abstinence. Acamprosate has a dose dependent efficacy(33).

In a meta-analysis, Mann et al found that the effect size for acamprosate on abstinent rates at 3, 6, and 12 months were 1.33 %, 1.50 %, and 1.95 %. The difference in continued abstinence at 12 months of treatment was 13.3 percent when compared to placebo(21).

Topiramate, an anti-epileptic, has an off label use in alcohol dependence. Its mechanism of action is by targeting both the GABA and glutamate brain pathways. It reduces craving(19).

Topiramateis an efficacious treatment for alcohol dependence. Studies have found it to be superior to placebo in decreasing the percentage of heavy drinking days(19).

The Selective Serotonin Reuptake Inhibitors (SSRIs) are helpful in maintaining abstinence from alcohol, especially in individuals with co-morbid depression(19).

Combination therapy involving sertraline and naltrexone was superior with the total abstinence of 54 % when compared to sertraline alone (28 %), naltrexone alone (21 %), or placebo(23 %) (19).

In a study comparing tri-cyclic antidepressant, desipramine versus placebo, desipramine decreased the relapse rate in comparison to the placebo(19).

Baclofen is a $GABA_B$ receptor agonist. It is hypothesized that baclofen reduces the severity of withdrawal symptoms and therefore inhibits craving. However, it is a less studied drug in terms of alcohol dependence treatment. It has a favorable side effect profile in individuals with liver cirrhosis(19).

Nalmefene is an opioid receptor agonist. It reduces the number of heavy drinking days by decreasing the craving and reducing the reinforcing properties of alcohol(19).

Ondansetron, is a 5-HT_3 receptor antagonist. It blocks the rewarding effects of alcohol. It was found to be more effective when compared to placebo(19).

Buspirone is helpful in alcohol use disorders by combating the underlying anxiety and does not have any effect on the drinking behavior (31).

In a randomized study done in Mumbai on 100 patients, it was found that Topiramate was helpful in decreasing craving in about 90 % patient and Disulfiram was helpful in maintaining a longer abstinent period in about 50 % of patients(1).

2.2 b. Non-Pharmacological treatment

Data suggests that any form of psychological treatment is better than no psychological treatment. However there is no substantial evidence to suggest superiority of one psychological treatment over the other. Psychological treatment alone can be beneficial in bringing about behavioral change. Psychological treatment strategies are highly effective in combination with medications in de-

addiction programs. Psychological interventions are an important part of a comprehensive treatment plan(34).Studies have shown that the psychological interventions along with psycho-social support are the corner stone in maintaining abstinence(21).

There are various psychological approaches to treat alcohol dependence. The strategies used include both individual and group therapeutic approaches. No specific psychological treatment plan has proven to be more effective than the other(35).

Much research has shown that psychological interventions can bring out significant behavior change and has a better long term prognosis. However, its inclusion into routine clinical practice is still lacking(34).

Cognitive behavior therapy, contingency management, motivation enhancement and brief intervention therapies have all shown improved outcomes during the therapy as well as at the end of the therapy(34).

A large number of trials have shown the efficacy of cognitive behavior therapy in alcohol use disorder. Cognitive behavior therapy utilizes variety of interventions like the motivational interventions, contingency management strategies, relapse prevention strategies and interventions for functional analysis(36).

Evidence for use of cognitive behavior therapy for cue exposure and relapse prevention strategies in alcohol use disorders have shown a better outcome with an increase in the number of abstinence days(34).

There is data to suggest 25-30 % abstinence rate with 12 step program along with cognitive behavior therapy(37).

Cue exposure strategies appear to be promising with regard to relapse prevention, but clinical trials and evidence for the same are lacking(34).

Contingency management techniques in alcohol use disorders have been shown to improved compliance to disulfiram and improve regularity in following up with the healthcare system(34).

Brief intervention strategies have found to be helpful in emergency settings and primary care settings. Prospective studies on brief intervention have shown a total of 20-30 % reduction in alcohol consumption at 6 and 9 months. The brief interventions are effective for individuals with harmful and hazardous alcohol use. Brief intervention are cost effective and have shown to be effective up to a 2 year follow up period(34).

Studies have shown that there is a clear dose dependent response to brief intervention counseling on the quitting rate. Intensive counseling increases the abstinence rate(34).

A meta-analysis of 22 studies has shown that motivation intervention is highly effective in reducing the hazardous drinking pattern within first 3 months of therapy. A 2011 Cochrane review, has shown that motivation enhancement can reduce alcohol consumption in contrast to no treatment. Motivation enhancement can be used alone or be used in combinations with other treatment modalities(34).

Relapse prevention strategies were formerly formulated as a part of maintenance program. Group and individual relapse prevention strategies have a good evidence based effectiveness in promoting abstinence rate(34).

A major randomized control trial, the Project MATCH, showed the 12 step protocol to be equally effective as cognitive behavior therapy and motivational intervention. However a Cochrane review of 12 randomized control trials in 2009, showed no major benefit of Alcoholic Anonymous group in reducing alcohol dependence(34).

The Behavioral Couples Therapy (BCT) assumes that there is a reciprocal relationship between relationship functioning and substance abuse. Substance use has a negative impact on the family relationship which leads to significant distress in the individual leading to increased substance use. Hence this form of therapy helps in addressing the partner's distress and improve the relationship functioning. A meta-analysis by Stanton & Shadish showed better adherence to therapy with better support system in the home environment and partner's involvement in the therapy(36).

Current evidence suggests that family therapy is a useful psychological intervention as it decreases the severity of alcohol use by promoting motivation and changing the locus of control to internal from external. Family therapy also aims at reducing anguish in family members, maintaining reasonable expectation from the individual and improving the family atmosphere. Family interventions include teaching problem solving skills which lead to better coping by the couple during the relapse periods(7).

Evidence has shown family therapy to be effective in adolescent population with alcohol use disorder(34).

The evidence pertaining to residential rehabilitation programs are sparse. A meta-analysis by Smith et al showed that there was no major difference in the effectiveness between residential rehabilitation programs and community residence for substance use disorders(34).

Occupational and social rehabilitation along with positive behavior change is pivotal in sustaining positive outcomes after an intensive therapy for alcohol use disorder (41).

Studies show that there is low implementation of these interventions. In addition, there are differences in training methodology worldwide (38).

2.3 Combination strategies

The combination of both psychological and pharmacological treatments have been shown to have the best outcome(34).

Combination therapy including counseling and medication like naltrexone has been shown to be effective in primary care settings. Screening and brief interventions have proved to be helpful to the "at risk" population in reducing the alcohol intake(12).

The COMBINE study showed that combination of naltrexone and behavioral therapies were more effective than any other combination therapies(34).

There are multiple studies suggesting that the combination therapy of naltrexone has shown best response with weekly cognitive behavior therapy. Individuals treated with naltrexone and cognitive behavior therapy has shown fewer relapse rates and longer abstinence periods when compared to cognitive behavior therapy or naltrexone therapy alone. Both naltrexone and cognitive behavior therapy are helpful in reducing craving and relapse prevention. However, the combination of naltrexone and cognitive behavior therapy was found to be superior to the combination of naltrexone and motivation enhancement therapy(38).

The successful treatment of alcohol dependence requires a multidimensional approach, combining pharmacotherapy, psychological intervention, psychosocial

support for the patient as well as family members and specific treatment for the underlying psychiatric co-morbid conditions(31).

2.4 Barriers to treatment

There are multiple barriers to treatment in case of substance use disorder. In many culture, substance abuse is a shameful and stigmatized affair, leading to restricted help seeking behavior and limited access to mental health care. Help seeking behavior is more constrained when it comes to women alcohol users. In the Asian culture, stepping out of the family to seek professional help is considered as a failure of the family members to help the individual. The Asian communities suffer a high stigma not just related to substance abuse but also to the help seeking behavior(39).

Low educational level and high level of acculturation of alcohol use has led to easy dismissal of signs and symptoms pertaining to alcohol use disorder, constricting the awareness to the possible pathways to care. The general mistrust of immigrant and minority communities hinders them from seeking treatment for alcohol use disorder(39). Transportation, financial, insurance issues have an complex interplay leading to dropouts from the treatment(39).

Denial, lack of problem awareness, trying to cope alone are the other factors identified in European countries as barriers to seek help(40).

Cultural issues may play a role in outcome. Involving the religious healers, adopting the traditional mode of healing like acupuncture, herbal medicines and assimilating

the cultural aspect in the treatment program could help in decreasing treatment drop-outs and increasing treatment adherence(39).

The patient may or may not respond to the initial treatment provided to them, hence an alternative patient tailored treatment plan must always be kept as an optional second line. Treatment modalities which seems to be attractive to the patient must be provided, so as to reduce the intrusiveness of treatment and to increase the adherence to care(12).

General health care physicians are often the earliest to encounter patients with substance dependence. Most receive little training and are inexperienced in providing early care for addiction. Hence, training in early detection of substance misuse and in first line strategies in addressing the issue, needs to be in-cooperated in the medical undergraduate and postgraduate programs(12).

2.5 Outcome

The outcome measures in alcohol use disorders include abstinence rates, reduction in use and improvement in social and physical wellbeing(41).

2.5 a. Outcome worldwide

A cohort study done in the Centre for Alcohol Addiction Treatment, in Ljubljana, Slovenia, involving 622 subjects showed a reduction in alcohol intake or abstinence in 53% patients at 3 months follow up period, 44.3 % at the end of 6month follow up period, 30.6 % at the end of 12 month follow up period. This study emphasized

on positive self-evaluation and stable social relationship as a key factor to abstinence. Telephone based after care and telephonic contacts with the therapist was found to be related with treatment success(41).

Studies on outcomes done in the United States have shown that 18 % of baseline heavy episodic drinkers continued the same drinking pattern at 25 years of follow up period. In this cohort, 19 % abstained from alcohol in one year of follow up and 10 % abstained at 3 years follow up period(8).

A 25 year follow up study from Sweden found that 61 % of the baseline patients continued to have problem drinking (8).

Studies done in Japan have been focusing more on “harm reduction” strategies, and promoting physical and social wellbeing. The Japanese promote the “controlled drinking” strategy as an integral part of treatment program for individuals who reject the complete abstinence norm. The treatment outcome in Japan was found to be 7 – 30 % abstinence in a 1-3 year follow up period(42).

In a study including 785 patients in the outpatient sample of project MATCH, a multisite clinical trial, focusing on self-efficacy of the patient and therapeutic alliance, it was found that patients with high baseline self-efficacy and good therapeutic alliance showed favorable outcome at the end of 1 year follow up. Patients with low self-efficacy but with good therapeutic alliance showed better

outcome when compared to patients with low self-efficacy and poor therapeutic alliance(43).

An outcome study by Lemke and Moos, with one year and five year follow up periods showed that older patients showed better outcome when compared to younger patients. They responded well to age-integrated substance treatment program and the 12 step self-help protocol(44).

An 8 year follow up study from United States, compared the outcomes among four treatment groups. These four groups consisted of untreated individuals, individuals who received help from the alcohol anonymous group, individuals who received formal treatment and the individuals who received help from both alcohol anonymous group and formal treatment. It showed that individuals who received some sort of treatment showed a better outcome in terms of abstinence when compared to the untreated group. The group which received Alcohol Anonymous help or formal treatment at least for one year of follow up showed better outcome in drinking indices at the end of 8 years. The formerly treated group continued to show consistent improvement in drinking indices throughout the 8 year follow up period(45).

In a 9 month follow up study conducted in a 262 patients from Amsterdam, with severe alcohol disorder, it was found that abstinent rates were higher for patients who were detoxified under medical supervision. The abstinence rate in medically

detoxified patients was 32.9 % and 18.9 % in the group who did not receive any medical assistance(46).

2.3 b. Outcome in India

There has been progress and expansion of evidence based psychological interventions for alcohol use disorders in India over the years(34).

Many Indian studies have shown good abstinence rate at follow up period. A study done by Desai et al (1993) showed a 36 % abstinence rate at 8 months follow up period. A two year follow up study by John and Kuruvilla (1991) showed a 50 % abstinence rate(47).

In India, treatment camps were first established by TTK hospital, in Manjakuddi in Tamil Nadu, which showed a good outcome rate at the end of 6 months(1).

A one year follow up study, done on 60 patients in JIPMER, Pondicherry, found an abstinence rate of 32.5 %, 35 % continued to drink but showed socio-occupational improvement and 32.5 % remained unimproved(47) .

In India, the use of Disulfiram is an important treatment modality. It gives an opportunity to the patient to meet the therapist, when they come to collect the medication. Hence, pharmacological treatment have a better outcome as it improves motivation, makes the hospital visits more meaningful and purposeful(47).

Studies have shown that maximum drop outs occur between 3 to 6 months of follow up. In an Indian study from a lower socio-economic status population belonging to slums has shown that weekly follow up at the clinics improves the outcome at the end of 3, 6 and 9 months(1).

A one year cohort study looked at99 urban slum residents in Bangalore, who received in-patient care in the de-addiction service of the National Institute of Mental Health and Neurosciences, Bangalore, India. Follow up at three, six, nine, and twelve months showed that continued monitored long term societal and community after care resulted in favorable outcome in alcohol dependence just as the case of any chronic medical illness(48).

The final outcome of treatment for alcohol use disorder should consider the family, social and occupational areas. The one year follow up study done by Abraham et al, showed that 35 percent patients showed a significant outcome in terms of social and occupational improvement despite continuing alcohol use on regular basis(47).

Alcohol use disorder is a major public health problem not just in developed countries but also in developing countries like India. There is a high prevalence of alcohol dependence in India. The proportion of patient who respond to treatment (interventions) is also high, suggesting an overall good outcome in India(47).

2.4 Factors associated with the outcome

The understanding about the exact mechanism and factors promoting a favorable outcome in alcohol use disorders is still unclear. There are multiple socio-demographic factors, alcohol use related factors and treatment related factors associated with the outcome(47).

The factors like severity of dependence, severity of withdrawal, psychiatric co-morbidity, personality traits, motivation, coping skills, genetic factors, social and economic factors, self-efficacy, family functioning are related to the outcome in alcohol use disorder(49).

2.4 a Factors associated with favorable outcome worldwide:

The protective factors associated with reduced alcohol use among adolescents include attendance at religious services, trusting relationship with parents, and seeking advice from parents(50).

In a Hungarian study religiosity was found to be a protective factor in alcohol use disorders(51).

Multiple factors like older age, less duration of alcohol use, social stability, less severity of alcohol related problems, a good pre-morbid functioning and past abstinence are indicative of a good outcome(47).

Studies comparing younger age of onset of alcohol use with older age of onset have shown that individuals with older age of onset of alcohol use have lower lifetime risk associated with severity and dependence pattern of use and are more compliant to treatment. Individuals with older age of onset of alcohol use respond well to treatment in terms of reducing the number of drinking days and the severity of alcohol use(52).

Studies have shown that older age of onset of alcohol use have better outcome due to better support system, better awareness of problem related to alcohol use and long term compliance with therapy(53).

Individuals having good family support and living in extended families have a better outcome(54).

Studies in the West have shown that people in families with better communication and relationship patterns have a more favorable treatment outcome(55).

Factors like stable partnership, long duration of treatment, engagement in self-help group and re-employment are related to better outcome(37).

The treatment modalities used are also an important factor in deciding the outcome. Psycho-educational groups aimed at improving the motivation, family therapy in addition to medication use has been found to be helpful in promoting better outcome. Community based models of care which are helpful in the ongoing support for the patients outside the hospital settings are associated with better outcome(1).

The continued community functioning, better coping skills, self-efficacy and motivation are related to favorable outcome(49). Self-efficacy in abstaining from drinking in high risk situations has been found to be a favorable predictor for abstinence as well as remission(20).

2.4 b Factors associated with unfavorable outcome worldwide:

The risk factors which have been associated with adolescent alcohol use include negative interaction with parents, alcohol dependence in parent, peer pressure, nicotine smoking, and conduct problems in childhood(50).

A study in the west found that onset of alcohol drinking before 14 years of age is more associated with development of dependence pattern within 10 years when compared to age of onset at or above 21 years, leading to poor outcome(56).

Evidence shows that earlier age of onset of alcohol use leads to an earlier and more severe dependence, with lower help seeking behavior, which in itself is a cause for poor outcome(57).Early age of onset of alcohol use leads to multiple psycho-social dysfunction in terms of educational, occupational, marital, political, social and community relationships which leads to negative outcome(58).

Studies in the West have shown that individuals belonging to monogamous family with significant interpersonal conflicts are more prone to hazardous alcohol use(51).

Data from the West has shown that individuals living in nuclear families have a poorer outcome(54).

Male gender, co-morbid substance abuse in form of nicotine smoking and others, medical co-morbidities like HIV and psychological distress associated to the physical illness are factors associated with poor outcome(59).

Personality disorders like antisocial and borderline personality disorders are predictors of poor outcome(60).

Factors like psychiatric co-morbidity, cognitive impairment, poor social support, financial problems, medication side effects, attitudes and beliefs towards treatment and lack of awareness about the problem are related to treatment drop out which leads to poor treatment outcome(61).

2.4 c Factors associated with favorable outcome in India:

An Indian study by Desai et al (1993), found that marital status, the duration of dependence, age of onset of dependence, post treatment stress score, and the number of treatment related abstinence days were the best predictor for alcohol use disorder therapies(47).

An Indian study had found that regular follow up with the family; continued peer and social support were protective factors against relapse. Individuals who stay in a

joint family and who are married have better outcome when compared to individuals who stay in a nuclear family or who are divorced or separated (62).

Family members provide ongoing motivation and emotional support, hence engagement of family members in the therapeutic process is associated with good outcome and involvement of family members should be an important aspect of any de-addiction program(63).

In the Indian context, pharmacological treatment in form of deterrent therapy, like Disulfiram, is a favorable factor associated with good outcome, as it promotes frequent hospital visits and interaction with the therapist, leading to enhancement of motivation during each hospital visit. The duration of Disulfiram use and high level of motivation are associated with good outcome(47).

The intermittent use of Disulfiram for short duration in high risk situations has also been suggested instead of prolonged use(47).

A follow up study done in 60 patients in JIPMER, Pondicherry, found out that none of the pre-treatment variables were related to favorable outcome, but the duration of Disulfiram use alone was associated with favorable outcome(47).

Bagadia et al (1982) had shown that 50 percent patient who continued to use Disulfiram showed moderate improvement(47).

The continued use of aversive therapy for about six months has been found to have a good outcome. The length of use of Disulfiram varies widely and is an important factor in determining the outcome(47).

The course and outcome studies suggested that regular follow up in the out-patient department are associated with good outcome(1).

Evidence suggests that on- going care after discharge, arrangement of sober housing, addressing the transportation needs for attending the appointments facilitate recovery. Studies have shown that self-help group promote abstinence and the health care professionals must encourage individuals to attend the self-help groups. These treatments are associated with good outcome(12).

An Indian study has shown that regular follow up in the out-patient department along with the caregivers, provides an opportunity to have brief psycho-education session with the care givers, and is associated with a better outcome(64).

Another study in North India has shown that subjects who regularly follow up in the out-patient care have a good treatment related outcome. The role of a social worker in motivating the subjects for regular follow up is described as pivotal(65).

A one year follow up study in Bangalore, showed that brief actual follow up or brief contacts or even telephone contacts helped in long term abstinence and relapse prevention. Efforts like supported employment helped in developing healthy work

habits helped patients to be in consistent contact with the counselors, which resulted in a better outcome(48).

A cohort study done in India showed that 33.3 % remained sober at a one year follow up period after attending the Alcohol Anonymous group and receiving continued support and motivation(66).

Regular clinical monitoring over the telephone has been shown to be helpful in maintaining recovery and can be included in the on-going care. A community based recovery support system is also helpful in maintaining recovery(12).

Continued telephone based after care and telephonic contacts with the patients were considered to be associated with a good outcome. Weekly telephonic monitoring, brief counseling and supportive group sessions had a good predictive value(41).

A one year cohort study conducted in 187 alcoholic men concluded that patient's motivation and continued care by the follow-up workers in their localities was positively related to long term sobriety(67).

2.4 d Factors associated with unfavorable outcome in India:

The studies in the past have found family history of alcoholism and lower proportion of abstinence days in the past being related to unfavorable outcome(47).

Studies have shown high relapse rate in families facing acute severe stress and chronic threatening environment(7).

Alcoholism in first degree relative, adverse childhood life events, family conflicts, lack of parental support, low parental educational attainment are risk factors for early onset of hazardous alcohol use which leads to poor outcome(51).

Young age of onset of alcohol use, low educational attainment, co-morbid substance use like smoking are related to poor outcome(51).

In an Indian study it was found that pretreatment variables like social problems, inter-personal problems, physical and mental health problems were associated with negative outcome in alcohol use disorders(8).

Factors like chronic use of alcohol, physical complication due to alcohol, co-morbid dissocial personality trait, unemployment have a poor outcome(37).

According to Lundwall and Beckland (1971), the follow up period for assessing the efficacy of any treatment should be at least one year. Self-reporting is not an affirmative or sufficient method for assessing the outcome. It is also important to collect corroborative reports from the primary care giver. The overall functioning of the individual should be taken into consideration, when evaluating the treatment outcome.

Hence, in the follow up visits outcome variables pertaining to socio-occupational functioning should also be considered. Multiple postal or telephonic reminders are also needed, to minimize the drop outs(47).

CHAPTER III

Aim

To study the outcome of patients with Alcohol Dependence Syndrome being treated in the psychiatric unit of a tertiary care centre.

Objectives

1. To study the prevalence of abstinence at the end of 3 month period of standard treatment in a cohort of newly registered patients with alcohol dependence in the psychiatric unit of a tertiary care centre.
2. To identify factors associated with favorable and unfavorable outcome.

CHAPTER IV

Methodology

4.1 Study area:

Christian Medical College and hospital, Vellore began in 1900, and offers both community and tertiary level services. The Department of Psychiatry is a 134 bedded facility, with 2acute care adult (Units I and II), 1adult rehabilitation, and 1 child and adolescent psychiatry units. The approximate number of new patients seen in one week by both of the adult acute care units is 180. Out of these 180 new patients, approximately 10 per week receive a diagnosis of alcohol dependence syndrome.

4.2 Study population:

The study included new patients who were diagnosed to be suffering from alcohol dependence syndrome according to the International Classification of Diseases and Related Health Problems (ICD-10) diagnostic criteria, who presented to Unit I and Unit II outpatient services on weekdays as well as weekends, from November 1st 2015 to April 30th 2016. Those fulfilling inclusion and exclusion criteria were invited to participate in the study. Written informed consent to participate was taken from the patient and the primary care giver at the initial visit. This included permission to interview them, document details from their medical records, make a specific appointment for the three month follow up interview, give a telephonic

reminder in the week prior to the second visit, and to review over the telephone should they not be able to keep the appointment.

4.3 Study Design: Hospital based cohort study

This is a prospective cohort study. Cohort designs are a type of observational study, in which a group of people with defined characteristics are followed over a time period to determine incidence of a particular outcome. It provides strong evidence for the causality and provides the temporal framework from the exposure to the outcome of interest.

4.4 Study period and screening:

The study proposal was approved by the Institutional Review Board and includes ethical clearance. The primary investigator assessed patients diagnosed with alcohol dependence syndrome in unit I and II from November 1st 2015 to April 30th 2016 on all weekdays. Valid written informed consent was taken from the patient and the relative at the time of recruitment. If the patient was deemed incapable of giving an informed consent, it was taken from the relative. It was obtained from the patient at a later date once the patient was eligible to give consent.

4.5 Inclusion Criteria:

1. All new adult patients with the primary diagnosis of alcohol dependence syndrome.
2. Patients giving valid informed consent to participate.

4.6 Exclusion criteria:

1. Patients with co-morbid major psychiatric disorders.
2. Patients with permanent cognitive deficits.

4.7 Data Collection:

The data regarding socio-demographic profile and details regarding alcohol use pattern was collected. The socio-demographic factors included age, gender, educational status, religion, occupation, socio-economic status, type of family structure and type of residence, distance of residence from hospital as well as liquor shop, adequacy of family support, physical co-morbidities. The family history included family history of alcohol use and neuropsychiatric illness. The alcohol use history of participant including age of onset of alcohol use, duration of dependence pattern, type of alcohol used, frequency of alcohol use per week, amount of alcohol used per day, number of times de-addiction treatment given in the past. Presence or absence of any recent adverse life events was recorded and presence or absence of legal problems due to alcohol use was recorded. The withdrawal symptoms and the severity of withdrawal were assessed by using the Clinical Institute of Withdrawal Assessment Scale. The severity of alcohol use was assessed using the Short Alcohol Dependence Data Questionniare. The Locus of Control was assessed using the Rotter's scale for locus of control. These assessments were made at the time of recruitment or as soon as the patient was cognitively stable enough to cooperate for testing.

The patient was contacted over the phone one week prior to the follow up date, for a reminder to come for the follow up visit. At this visit, interview was conducted with the patient and the primary care giver. Patients and caregivers who were not able to come for follow up interview due to unavoidable reasons were interviewed over the phone. Their clinical records were reviewed. The information collected in the last follow up visit and from the chart review was taken for the final analysis. All the data was kept confidential and personal identities were removed to avoid tracing of the individual.

4.8 Variables/ Tools

Socio demographic data:

The socio-demographic data proforma included information about age, sex, marital status, educational status, type of employment and type of family. Details about alcohol use included age of onset of use, duration of use, severity of alcohol use, severity of withdrawal symptoms and locus of control.

A semi structured interview was conducted to collect these and the details of the clinical syndrome.

The tools used in this study are interviewer rated with good reliability and validity.

Short Alcohol Dependence Questionnaire (SADD)

SADD was used to assess the severity of alcohol use. It has a good validity and reliability and is used widely. It has also been validated in Tamil. It has 15 items which are rated in Likert scoring system from 0-3 (0- never, 1-sometimes, 2-often, 3-nearly always). It takes less than 5 minutes to complete. A score of 1-9 is

suggestive of low dependence, 10-19 is suggestive of medium dependence and > 20 is suggestive of severe dependence.

The Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-Ar)

This is a scale devised to measure the severity of withdrawal symptoms. It has 10 items and 9 of them are rated from 0-7, and 1 is rated 0-4. It takes 5 minutes to administer this scale. The maximum score possible is 67.

Rotter's scale for Locus of Control

This was used to assess whether the locus of control was external or internal. It takes about 10 minutes to administer the scale. It has 23 items, each item presenting two statements: one revealing internal locus of control, and one revealing external locus of control. The respondents choose from the two statements. If chosen by the respondent, only the statement pertaining to external locus of control is scored. Hence a high score is indicative of external locus of control. This scale has been translated in 40 languages worldwide.

The second assessment interview was done after 3 months and included outcome measures of total abstinence, number of abstinence days, number of lapses and relapses.

Dealing with Bias

Selection bias was minimized by recruiting all new eligible patients with alcohol dependence syndrome who presented to the outpatient department of Unit I and II, Psychiatry, CMC, Vellore during the study period.

The baseline profiles of the two groups (those who completed the study and those who did not) were compared to check if they were similar.

4.9 Sample size:

Sample size was calculated using the formula $n= 4pq/d^2$ where,

Type 1 error (α) is fixed as 5%,

- p is the expected prevalence of people who are completely abstinent after a defined period of follow up. An estimate of 33% as found from a previous study was used.
- q is (100-p), hence 100-33= 67 %
- d is the absolute precision which was kept at 10 %
- Hence the calculated sample size was 88.

4.10 Participant enrolment and follow-up:

A total of 115 patients were eligible, and all consented to participate in the study. After a period of 3 months they were reminded by phone to come for the second assessment, one week prior to the expected date. 17 patients did not come for the second followup, and did not respond to calls over the phone.

Of the 98 who followed up, 5 patients came for second assessment in person and the remaining 93 patients finished their second assessment over the phone. The details obtained in the second review was cross-checked and supplemented with information from the outpatient chart regarding number of reviews, medication received, and number of abstinence days. The details were also corroborated with

the primary care giver. Data analysis was done for the 98 patients who finished the second assessment.

4.11Statistical method: Descriptive statistics were used to analyze the socio demographic profile of the participants. Frequencies were calculated for the categorical variables. Means as well as the standard deviations were calculated for the continuous variables. The categorical variables were presented using bar plots and continuous variables using histogram plots. The association between the categorical variables were performed using Chi-square test and Fisher's exact test. The factors associated with favourable outcome weresubjected to a multivariate logistic regression analysis. The factors which were significant at 20% alpha level were included in the multivariate analysis. The significance level of multivariate analysis was 5% alpha level ($p<0.05$). Odds ratio and 95% confidence interval were also presented along with p values. Data was entered using Epidata 3.0 and was analysed using SPSS 16.0.

CHAPTER V

Results

5.1 Response Rate:

The total number of participants recruited for the study was 115. All these 115 participants gave the written consent for participation in the study. The initial data at index visit was completed for the 115 recruited participants.

Data for the second assessment after 3 months was complete for 98 participants. 5 participants followed up in person. The remaining 93 were followed up over phone. Out of the 98 participants who followed up, 30 were completely abstinent at the end of 3 months follow up period and 68 were not abstinent.

Data was incomplete for 17 participants at the end of the 3 month study period. Of these, 9 did not come for any repeat visits, and were not contactable via phone after 3 months. Thus second assessment could not be performed for these 9 participants and no information about their abstinence status could be obtained.

For the remaining 8 participants, some information was available from their medical records, but we were not able to follow them up in person or on the phone after 3 months.

Number of patients recruited (n=115)

The total number of patients who gave consent= 115

The total number of patients who completed the initial assessment = 115

Patients with incomplete data (17)

Did not come after first visit and could not be contacted = 9

Could not be contacted after 3 months period = 8

Total number of patients who followed up (115 - 17 = 98)

Came in person for second assessment = 5

Finished second assessment over phone = 93

Status at follow up (98)

Number abstinent = 30

Number not abstinent = 68

Table 1: Socio demographic data of 98 participants (followed up at the end of 3 months follow up period)

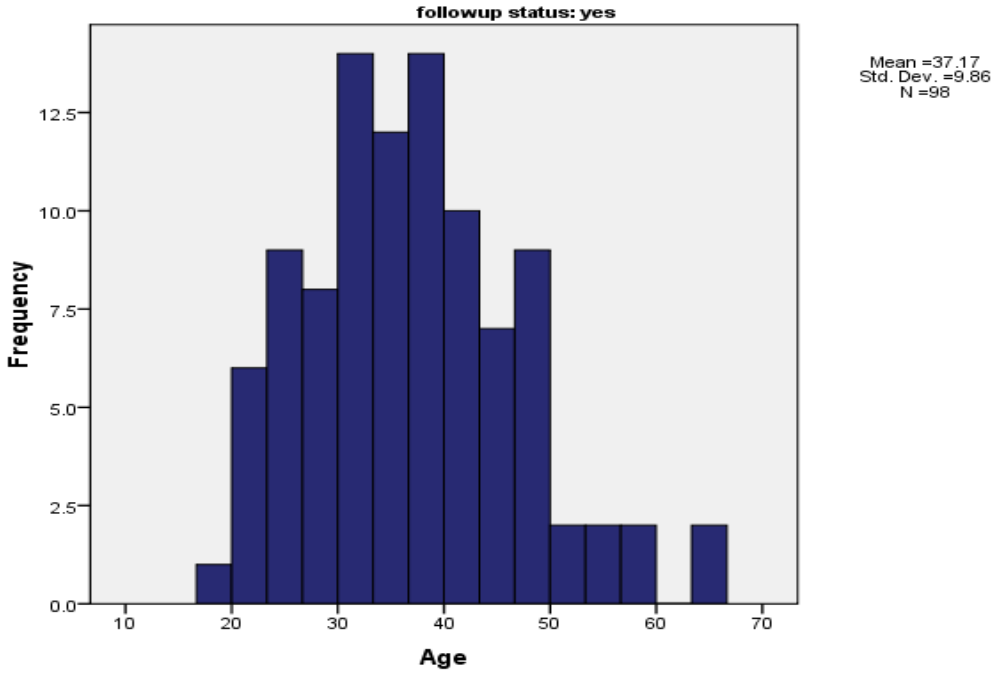
Variables	Frequency (n)	Percentage (%)
Gender		
Male	97	99.0
Female	1	1.0
Age		
<40 yrs	60	61.2
>=40 yrs	38	38.8
Education		
No formal education	4	4.1
Primary	10	10.2
Higher Primary	49	50.0
High School	16	16.3
Intermediate	4	4.1
UG/PG	13	13.3
Professional	2	2.0
Marital Status		
Married	74	75.5
Single	20	20.4
Separated	4	4.1
Occupation		
Unemployed	10	10.2
Unskilled	54	55.1
Semiskilled	7	7.1
Skilled	21	21.4
Semiprofessional	5	5.1
Professional	1	1.0
Type of Family		
Nuclear	53	54.1
Joint	4	4.1
Extended	41	41.8
Type of Residence		
Urban	41	41.8
Rural	57	58.2
Socio-economic status		
Upper middle class	1	1.0
Middle class	47	48.0

Lower class	50	51.0
Religion		
Hindu	90	91.8
Christian	8	8.2
Distance of area of residence from the hospital		
=<50 km	63	64.3
>50 km	35	35.7
Distance of the liquor shop from the area of residence		
=<1 km	63	64.3
>1 km	35	35.7
Does the patient have adequate family support		
Yes	94	95.9
No	4	4.1

5.2Socio demographic data of 98 participants:

Age:

The sample age ranged from 19 to 66 years. The mean was 37.17 years and the standard deviation was 9.86 years.



Gender: 114 men and 1 woman were recruited in the study. 97 men and 1 woman followed up at the end of 3 months follow up period. Hence the sample included 99 % males and 1 % females.

Educational status of the participants: The educational level of participants ranged from no formal education (n=4, 4.1 % of the sample who followed up) to having professional education (n=2, 2% of the sample who followed up). Majority of the participants had studied up till higher primary school(n= 49, 50 %).

Marital Status: 74 (75.5%) participants were married,20 **(**20.4 %) were single and 4 (4.1 %)were separated.

Occupation: The occupational status of participants ranged from unemployment to professional employment. Majority participants (n=54, 55.1 %) had unskilled employment. Only 1participant (1%) had professional employment.

Type of family:53 (54.1 %) participants belonged to nuclear family, 41(41.8 %) participants belonged to extended family and 4 (4 %) participants belonged to a joint family.

Type of residence: Majority participants (n=57, 58.2 %) resided in a rural area and the remaining 41 participants (41.8 %) resided in an urban area.

Socio-economic Status: The majority of participants belonged to lower socio-economic status (n=50, 51%), 48 participants (48%) belonged to middle socio-economic status and only 1 (1 %) belonged to upper middle class.

Religion: The Hindus were 90 (91.8 %)and Christians were 8 (8.2 %).

Distance of area of residence from the hospital: 63 (64.3%) participants lived within 50 kilometers from the hospital and 35 (35.7%) lived beyond50 kilometers distance from the hospital. The minimum distance was 1 kilometer and maximum was 300 kilometers with a median of 40 kilometers.

Distance of liquor shop from the area of residence:63 participants (64.3 %)lived within 1 kilometer from the liquor shop and 35 (35.7 %)lived beyond 1 kilometer from the liquor shop. The minimum distance was 0.1 kilometer and maximum was 10 kilometers with a median of 1.0 kilometers.

Adequate family support: 94 participants (95.9 %) reported adequate family support and 4 (4.1 %) participants felt they did not have adequate family support.

Table 2: Family history related to alcohol use disorder

Variable	Frequency (n)	Percentage (%)
Family history of alcohol use		
Present	75	76.5
Absent	23	23.5
If yes ,degree of Relatedness of the family member with the Participant		
1st degree	67	89.3
2nd degree	6	8.0
3rd degree	2	2.7
Treatment given to family member for alcohol use		
yes	10	13.3
no	65	86.7
Family history of neuropsychiatric illness		
yes	14	14.3
no	84	85.7
If yes, Type of neuropsychiatric illness		
Psychotic	7	50.0
Neurological	1	7.1
Other	6	42.9

5.3Family history of alcohol use:75 participants (76.5 %)had a family history of alcohol use. Among these 75 participants, 67 (89.3 %) had first degree relatives using alcohol, 6 (8 %) had second degree relatives using alcohol and 2 (2.7 %) had third degree relatives using alcohol. Family member of only 10 participants (13.3%) received treatment for alcohol use disorder.

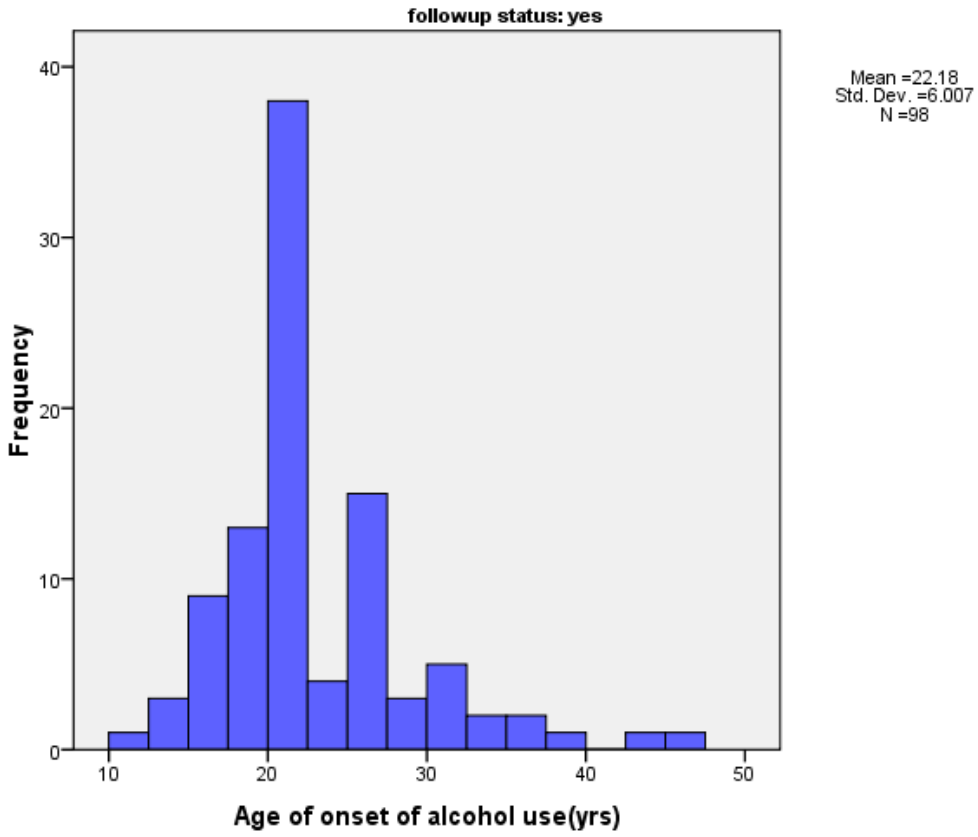
Family history of neuropsychiatric illness: 14 (14.3 %) participants had a family history of neuropsychiatric illness. Psychosis at 50% (n=7) was the most common illness. .

Table 3: Alcohol use history of the participants

Variable	Frequency (n)	Percentage (%)
Age of onset of alcohol use (years)		
<25 yrs	68	69.4
>=25 yrs	30	30.6
Total duration of Alcohol use		
<10 yrs	28	28.6
10 – 19 yrs	42	42.9
>=20 yrs	28	28.6
Total duration of alcohol dependence		
<10 yrs	75	76.5
>= 10 yrs	23	23.5
SADD score		
10-19 medium dependence	15	15.3
>=20 high dependence	83	84.7
CIWA- Ar		
<10	64	65.3
>=10	34	34.7
Rotter's score		
12-23 (external)	58	59.2
Type of Alcohol used		
Brandy	56	57.1
Whiskey	3	3.1
Rum	15	15.3
Others	24	24.5
Frequency of alcohol use per week		
<= 4 days	10	10.2
5-7 days	88	89.8
Total amount of alcohol used per day		
<1/2 liter	33	66.3
>= ½ liter	65	33.7
Any previous de-addiction given		
Yes	10	10.2
No	88	89.8
How many times previous de-addiction given		
once	5	50
twice	3	30
Thrice	2	20

5.4Age of onset of alcohol use: The age of onset of alcohol use ranged from 10 years to 45 years, with a mean age of 22.18 years and a standard deviation of 6.007 years.

68 (69.4 %) participants had started using alcohol before the age of 25 years and 30 participants(30.6 %) at or after 25 years of age.



Alcohol use history:

The total duration of alcohol use ranged from 1 year to 46 years with a median of 15 years. About 42.9 % (n= 42) had a total duration of alcohol use of 10 -19 years, 28

participants (28.6 %) had a duration of less than or equal to 10 years, 28 (28.6%) had a duration of more than 20 years.

The duration of dependence ranged from a minimum of 0.2 years to maximum of 30 years with a median of 4 years.

75 participants (76.5 %) had a total duration of dependence of less than 10 years and 23participants (23.5 %) had a total duration of dependence of 10 years or more.

Brandy was the most commonly used liquor, being used by 56 participants (57.1 %). Rum was used by 15 participants (15.3 %) and whiskey was used by 3 participants (3.1%). 24 participants (24.5%) had no specific preference and used a variety of alcoholic beverages, which was clubbed together in the category of others.

88 participants (89.8 %) drank alcohol in a frequency of 5-7 days per week and 10 (10.2 %) drank alcohol in a frequency of 4 days or less in a week. The frequency of alcohol use in a week ranged from a minimum of 3 days to a maximum of 7 days, with a median of 7 days.

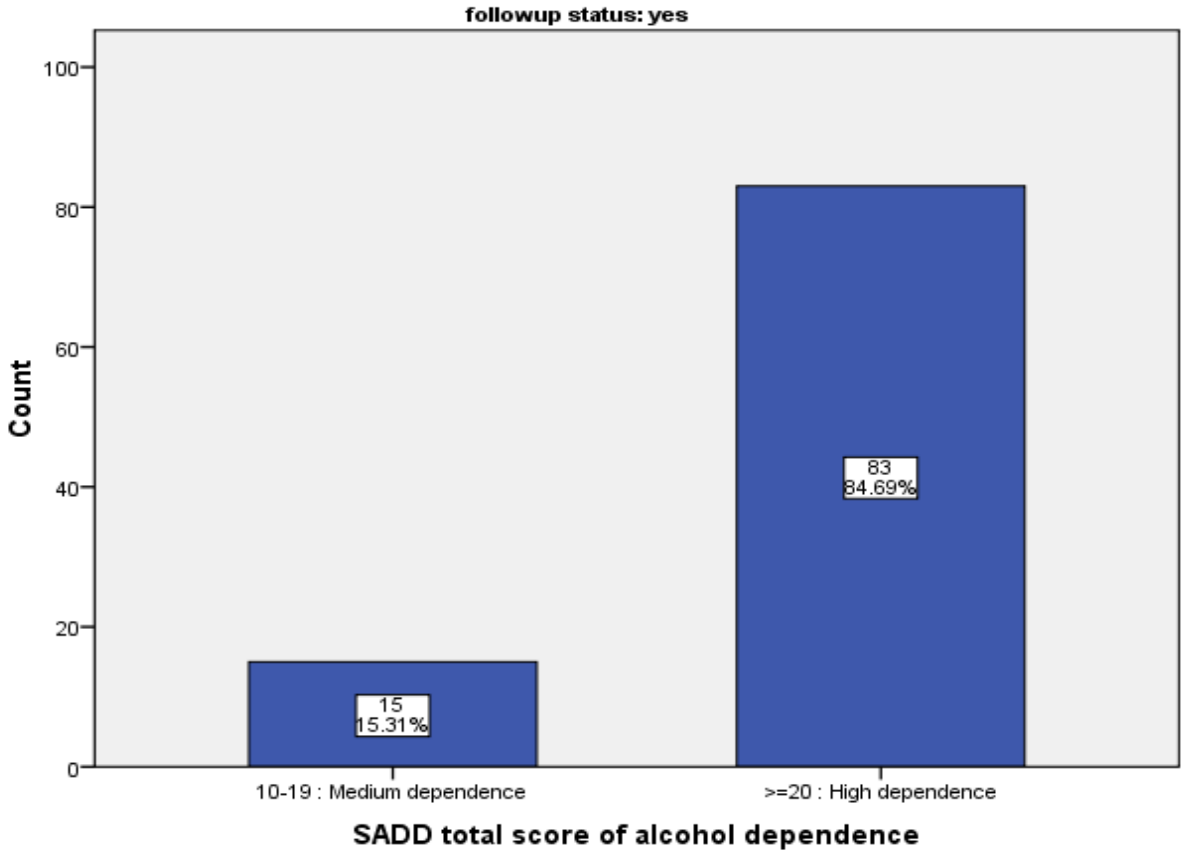
65 participants (66.3 %) consumed less than 50 units of alcohol per day and 33 (33.7 %) consumed equal to or more than 50 units of alcohol per day. The total amount of alcohol use per day ranged from 18 units to 100 units with a median of 36 units.

Out of the total 98 participants 10 participants (10.2%) had received de-addiction treatment in the past. Out of these10 participants, about 5 participants (50%) had

received de-addiction once, 3 participants had received it twice and 2 participants received thrice.

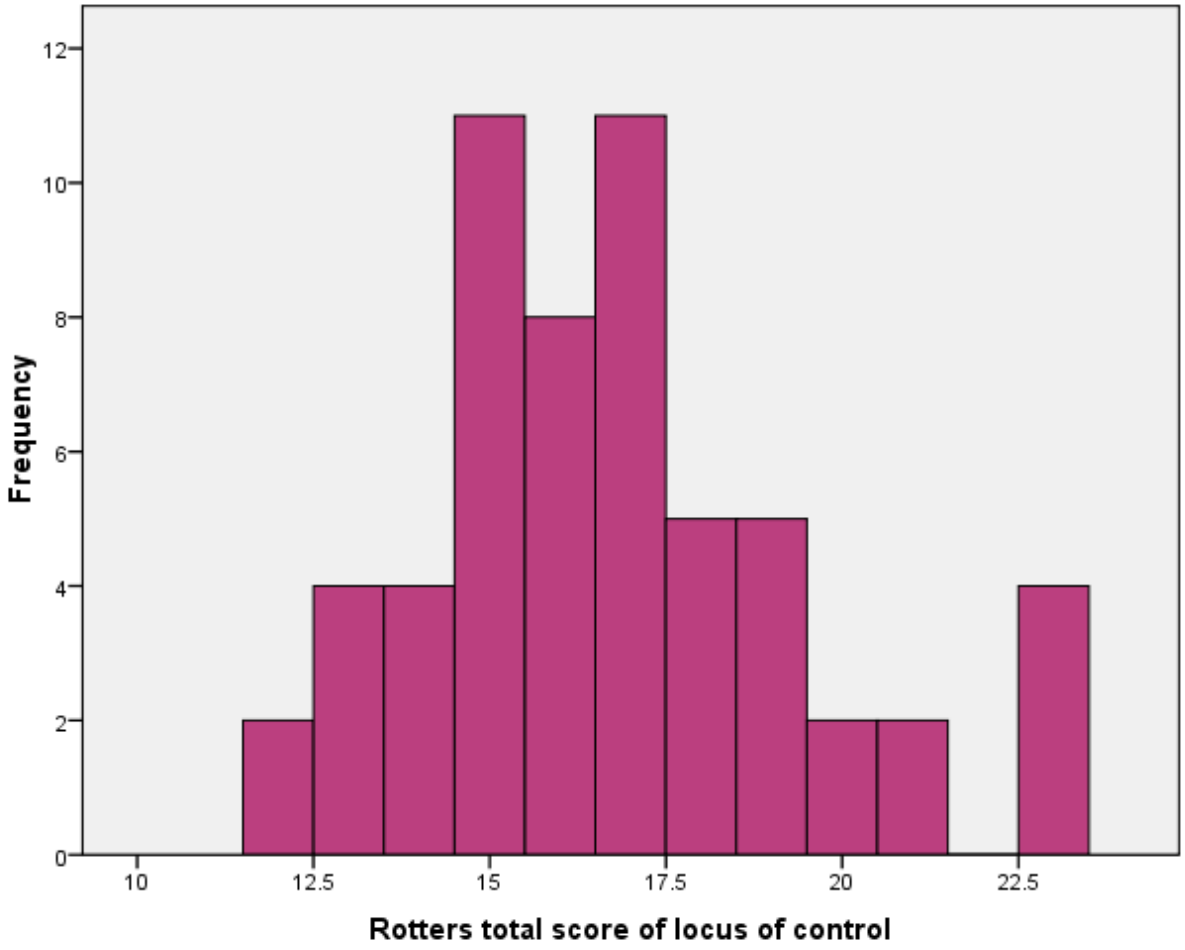
SADD, Rotter's locus of control and CIWA-Ar scores of the 98 participants

A total of 83 participants (84.7 %) had a high dependence score of more than or equal 20. The remaining 15 participants (15.3%) had a medium dependence score.



SADD score: The SADD score ranged from a minimum of 10 to a maximum of 42, with a mean of 27.86 and standard deviation of 7.106.

Rotter's locus of control (external locus): The scores ranged from 12 to 23, with a mean of 16.74 and standard deviation of 2.705.



(n=58) (follow up=yes and score>=12)

58 participants (59.2%) have an external locus of control.

CIWA–Ar: The CIWA-Ar scores ranged from 0 to 49, with a median of 6.

64 participants (65.3 %) had a CIWA–Ar score of less than10 and 34 participants (34.7 %) had a score of 10 or more. (Table 3)

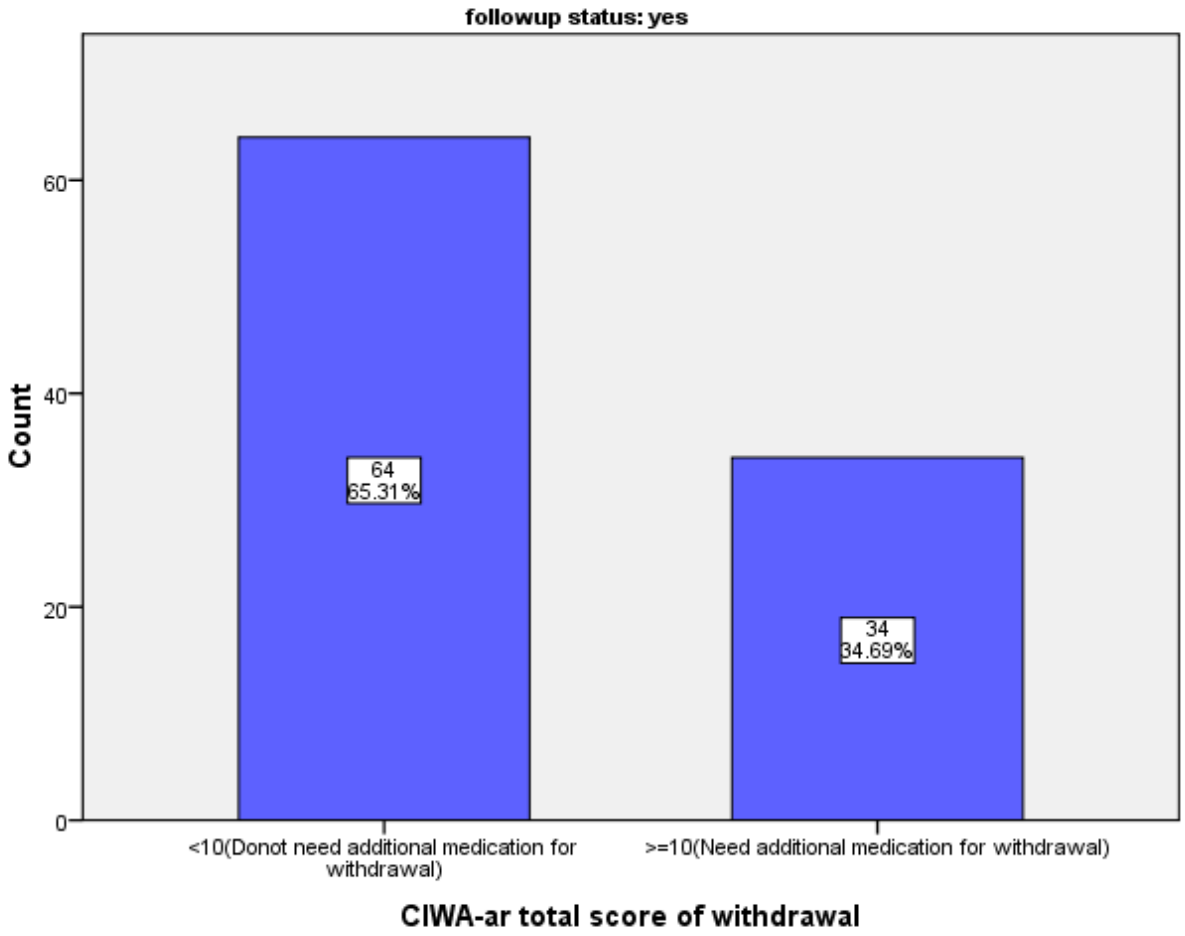


Table 4: Physical, Legal, Financial complication due to alcohol use disorders in the 98 participants

Any Physical co-morbidity in the participant	Frequency (n)	Percentage %
Yes	27	27.6
No	71	72.4
If yes, Is the physical co-morbidity an effect of alcohol use		
Yes	10	37
No	17	63
Legal implication		
Yes	6	6.1
No	92	93.9
Financial Problems		
Yes	23	23.5
No	75	76.5
Recent adverse life events		
Yes	10	10.2
No	88	89.8

5.5 Various complications due to alcohol use

27 participants (27.6%) had physical co-morbidities. Out of these 27 participants, only 10 participants (37 %) had physical complications due to alcohol use.

Legal consequences due to alcohol use were present only in 6 participants (6.1%).

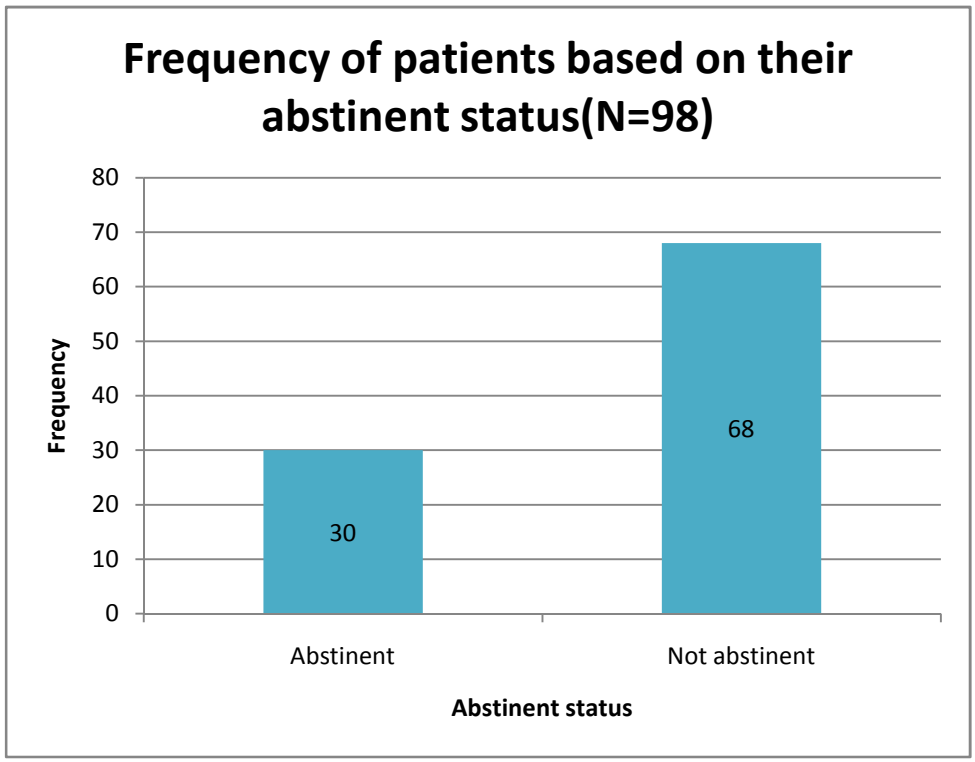
Financial problems were present in 23 participants (23.5 %). Majority of the participants (n=75) (76.5 %) did not report any financial consequences.

10 participants (10.2 %) had had recent adverse life events.

Table 5: Abstinence Status at 3 months follow up for the 98 participants

Variable	Frequency (n)	Percentage (%)
Complete Abstinence	30	30.6
Incomplete Abstinence	68	69.4
Any lapses		
Yes	68	69.4
No	30	30.6
Total number of lapses		
One	58	85.3
Two or more	10	14.7

Abstinence status in 98 participants



30 participants were abstinent at the end of 3 months follow up period (30.6 %). 68 (69.4%) participants had incomplete abstinence at the end of the follow up period.

5.6 Number of lapses: 68participants (69.4 %) had lapsed and used alcohol.

The minimum number of lapse was 1 and maximum number of lapse was 11, with a median of 1.

Among the participants who lapsed, 58 participants (85.3 %) lapsed only once in the 3 months follow up period. The remaining 10 participants (14.7 %), lapsed two or more times.

92.5 % of participants lapsed in the initial 45 days of the follow up period and 7.5 % participants lapsed in the last 45 days of the follow up period.

Table 6: Treatment related variables

Variable	Frequency (n)	Percentage (%)
Type of treatment received		
In-patient	1	1
Out patient	97	99
Did the patient receive emergency room care		
yes	13	13.3
no	85	86.7
Type of treatment received		
Pharmacological	53	54.1
Non-Pharmacological	3	3.1
Both	42	42.9
Did patient attend any group		
yes	7	7.1
no	91	92.9
AA group		
no	98	100
Alcohol group in the hospital		
yes	7	100
Did the patient attend the occupation therapy group		
yes	1	16.7
Did the patient receive Disulfiram		
yes	8	8.2
no	90	91.8
Did the patient receive anti-craving agent		
yes	1	
no	97	99
Any alternative treatment given		
yes	6	6.1
no	92	93.9

5.7 Treatment related variables

One participant (1%) received in-patient care and the remaining 97 (99%) were treated on out-patient basis.

13 participants (13.3%) received emergency care room treatment as they were in complicated alcohol withdrawal state. The remaining 85 (86.7 %) did not require admission.

Majority of the participant (n= 53) (54.1%) received only pharmacological treatment. 42 participants (42.9%) received both pharmacological and non-pharmacological treatment. 3 participants (3.1%) received only non-pharmacological treatment.

Only 7 (7.1%) out of the 98 participants attended alcohol group sessions. All of these participants attended the alcohol group in the hospital. None of the participants attended the Alcohol Anonymous group.

8 participants (8.2%) received Disulfiram.

Only 1 participant (1%) received anti-craving agent in the form of Naltrexone.

6 participants (6.1%) reported taking alternative treatment in the form of Ayurvedic or Homeopathic treatment from elsewhere, along with the allopathic treatment from our hospital. The remaining 92 participants (93.9%) received only allopathic treatment.

Table 7: Regularity of follow up visits and adherence to medication

Was patient coming for regular review visits		
yes	28	28.6
no	70	71.4
Was patient regular on medications		
yes	26	26.5
no	72	73.5
Did patient continue treatment in this hospital after lapse/relapse		
yes	12	17.9
no	55	82.1

5.8 Follow up visits and adherence to medication

28 participants (28.6%) were regular for review visits and 70 participants (71.4 %) were irregular.

26.5 % (n=26) participants were regular on medication and (73.5 %) (n=72) participants were not compliant with medications.

Out of the total participants who lapsed into alcohol use, 82.1 % did not continue treatment in this hospital and 17.9 % continued treatment in this hospital.

Table 8: Factors associated with complete abstinence (N=98).

Variables	Complete abstinence (N=30)	Univariate	Multivariate	
	n(%)	P Value	OR(95%CI)	p value
Age				
<40 yrs	17(28.3)	.538		
>=40 yrs	13(34.2)			
Marital status				
Married	22(29.7)	.270		
Single	8(40.0)			
Separated	0(0.0)			
Type of family				
Nuclear	17(32.1)		3.0(.6-14.4)	.175
Joint	3(75.0)	.105	19.0 (.2-1769)	.204
Extended	10(24.4)		1.0	
Education				
No formal education	1(25.0)			
Primary schooling	6(60.0)			
Higher Primary	16(32.7)	.281		
High School (10^{th})	2(12.5)			
Intermediate Schooling (12^{th})	1(25.0)			
College (UG/PG)	3(23.1)			
Professional Course	1(50.0)			
Occupation				
Unemployed	3(30.0)			
Unskilled	14(25.9)			
Semiskilled	2(28.6)	.608		
Skilled	8(38.1)			
Semiprofessional	2(40.0)			
Professional	1(100)			
Economic Status				
Upper Middle class	0(0.0)			
Middle class	15(31.9)	.784		
Lower class	15(30.0)			
Religion				
Hindu	26(28.9)	.244		

Christian	4(50.0)			
Area of residence				
Urban	15(36.6)	.277		
Rural	15(26.3)			
Distance of area of residence from the hospital				
<=50 km	16(25.4)	.133	.5(.1-2.0)	.326
>50 km	14(40.0)		1.0	
Distance of liquor shop from area of residence				
<= 1 km	21(33.3)	.433		
>1km	9(25.7)			
Family history of alcohol use				
Present	23(30.7)	.983		
Absent	7(30.4)			
Degree of relatedness of family member to the subject				
1st degree	18(26.9)		-	.999
2nd degree	3(50.0)	**.049**	-	.999
3rd degree	2(100)		1.0	
Treatment for alcohol use given to relative				
yes	4(40.0)	.484		
no	19(29.2)			
Family history of neuropsychiatric illness				
yes	6(42.9)	.350		
no	24(28.6)			
Type of neuropsychiatric illness in family member				
Psychotic	4(57.1)			
Neurological (seizures)	0(0.0)	0.459		
others	2(33.3)			
Any physical co-morbidity in the				

patient				
yes	7(25.9)	.535		
no	23(32.4)			
Is the physical co-morbidity after effect of alcohol use				
yes	3(30.0)	>.999		
no	4(23.5)			
Does patient have adequate family support				
yes	30(31.9)			
no	0(0.0)	.309		
Age of onset of alcohol use				
<25 yrs	24(35.3)	.130	4.7(.9-24.6)	.069
>= 25 yrs	6(20.0)		1.0	
Duration of alcohol use		.		
<10 yrs	7(25.0)	475		
10-19 yrs	12(28.6)			
>= 20 yrs	11(39.3)			
Duration of dependence				
<10 yrs	23(30.7)	.983		
>= 10 yrs	7(30.4)			
Number of days of alcohol use per week				
<=4 days	4(40.0)	.489		
5-7 days	26(29.5)			
Amount of alcohol use per day		.		
<1/2 liter	21(32.3)	.609		
>=1/2 liter	9(27.3)			
Any previous de-addiction given				
yes	3(30.0)	>.999		
no	27(30.7)			
If yes, the number of times the treatment given				
once	1(20.0)	0.728		

twice	1(33.3)			
thrice	1(50.0)			
Legal implication				
Present	2(33.3)	>.999		
Absent	28(30.4)			
Financial problems				
Present	6(26.1)	0.590		
Absent	24(32.0)			
Any recent adverse life event				
Present	2(20.0)	.719		
Absent	28(31.8)			
Any lapses				
present	0(0.0)	**<.001**		
absent	30(96.8)			
Was patient regularly coming for follow up				
yes	19(67.9)	**<.001**	32.8(5.5-194.6)	**<.001**
no	11(15.7)		1.0	
Type of treatment given				
In-patient	1(100)	.306		
Out-patient	29(29.9)			
Did patient receive emergency room treatment				
yes	5(38.5)	.529		
no	25(29.4)			
Type of treatment received				
pharmacological	10(18.9)	**.021**		
Non-pharmacological	1(33.3)			
both	19(45.2)			
Did patient attend any group				
yes	2(28.6)	>.999		
no	28(30.8)			
Alcohol MHC group				
yes	2(28.6)			
Occupation therapy group				

Yes	1(100)	.333		
No	(20)			
Did patient receive disulfiram				
yes	7(87.5)	**.001**		
no	23(25.6)			
Did patient receive any other anti-craving agent				
yes	0(0.0)	>.999		
no	30(30.9)			
Any other alternative treatment taken				
yes	2(33.3)	>.999		
no	28(30.4)			
Was patient regular on medication				
yes	17(65.4)	**.000**		
no	13(18.1)			
SADD total score				
10 – 19 (medium dependence)	10(66.7)	**.002**	5.3(.6-48.2)	.137
>= 20 (high dependence)	20(24.1)		1.0	
CIWA –ar				
<10	23(35.9)	.117	2.2(.5-11.0)	.329
>= 10	7(20.6)		1.0	
Rotter's total score				
12-23 (external locus of control)	16(27.6)	.434		

5.9 Factors associated with complete abstinence after the 3 month follow up period

The factors associated with complete abstinence after the 3 months follow up period were studied using Chi-square test and Fisher's exact test and multivariate logistic regression analysis. The significant predictors of complete abstinence in the unadjusted analysis (univariate analysis) ($p<.05$)were found to be the degree of relatedness of the family member using alcohol to the participant, the SADD score, regularity of review visits to the hospital, the type of treatment received, treatment with Disulfiram and medication adherence.

Significant Factors associated with complete abstinence	P value
Degree of relatedness of the family member using alcohol with the participant	.49
SADD Score	.002
Regularity of review visits to the hospital	.001
The type of treatment received	.021
Disulfiram received	.001
Medication adherence	.000

Regularity with review visits, good adherence to medication, being prescribed Disulfiram, and receiving both pharmacological treatment and non-pharmacological treatment were significantly associated with abstinence.

The participant who had third degree relative using alcohol were more likely to be abstinent when compared to participants who had first and second degree relative using alcohol.

In the adjusted analysis (multivariate) ($p<0.05$), the only factor associated with complete abstinence was the regularity for review visits to the hospital.

5.10 Socio-demographic profile of participants who lost to follow up:

The age ranged from 7 to 55 years with a mean of 40.29 years and standard deviation of 8.13 years. All the 17 individuals were male. 14 individuals were married, 2 single and 1 widower. 11 stayed in nuclear family, 5 in extended family and 1 in joint family. Majority had primary schooling and only one studied professional course. Majority were unskilled laborers and only one had a professional job. 13 belonged to lower socio-economic status, remaining belonged to middle socio-economic status. Majority were Hindus and majority stayed in rural area.

The minimum distance of residence from the hospital was 7 kilometers and maximum was 100 kilometers with a median of 45kilometers.

Table 9: Comparison between follow up and lost to follow up groups (N=115).

Variables	Follow up status Yes (N= 98)	Follow up status No (N=17)	P value
	n(%)	n(%)	
Age			
<40 yrs	60(61.2)	9(52.9)	.520
>=40 yrs	38(38.8)	8(47.1)	
Marital status			
Married	74(75.5)	14(82.3)	.068
Single	20(20.4)	2(11.8)	
Separated	4(4.1)	0(0.0)	
Widow	0(0.0)	1(5.9)	
Type of family			
Nuclear	53(54.1%)	11(64.7)	0.618
Joint	4(4.1)	1(5.9)	
Extended	41(41.8)	5(29.4)	
Education			
No formal education	4(4.1)	1(5.9)	.478
Primary schooling	10(10.2)	4(23.5)	
Higher Primary	49(50)	6(35.3)	
High School (10^{th})	16(16.3)	3(17.6)	
Intermediate Schooling (12^{th})	4(4.1)	2(11.8)	
College (UG/PG)	13(13.3)	1(5.9)	
Professional Course	2(2.0)	0(0.0)	
Occupation			
Unemployed	10(10.2)	2(11.8)	.528
Unskilled	54(55.1)	10(58.8)	
Semiskilled	7(7.1)	0(0.0)	
Skilled	21(21.4)	4(23.5)	
Semiprofessional	5(5.1)	0(0.0)	
Professional	1(1.0)	1(5.9)	
Economic Status			
Upper Middle class	1(1.0)	0(0.0)	.147

Middle class	47(48.0)	4(23.5)	
Lower class	50(51.0)	13(76.5)	
Religion			
Hindu	90(91.8)	15(88.2)	.641
Christian	8(8.2)	2(11.8)	
Area of residence			
Urban	41(41.8)	5(29.4)	.334
Rural	57(58.2)	12(70.6)	
Distance of area of residence from the hospital			
<=50 km	63(64.3)	13(76.5)	.327
>50 km	35(35.7)	4(23.5)	
Family history of alcohol use			
Present	75(76.5)	9(52.9)	.072
Absent	23(23.5)	8(47.1)	
Degree of relatedness of family member to the subject			
1st degree	67(89.3)	9(100)	.588
2nd degree	6(8.0)	0(0.0)	
3rd degree	2(2.7)	0(0.0)	
Any physical co-morbidity in the patient			
yes	27(27.6)	4(23.5)	>.999
no	71(72.4)	13(76.5)	
Is the physical co-morbidity after effect of alcohol use			
yes	10(37.0)	2(50.0)	.630
no	17(63.0)	3(17.6)	
Does patient have adequate family support			

yes	94(95.9)	14(82.4)	.065
no	4(4.1)	3(17.6)	
Age of onset of alcohol use			
<25 yrs	68(69.4)	8(47.1)	.073
>= 25 yrs	30(30.6)	9(52.9)	
Duration of alcohol use			
<10 yrs	28(28.6)	5(29.4)	.107
10-19 yrs	42(42.9)	11(64.7)	
>= 20 yrs	28(28.6)	1(5.9)	
Duration of dependence			
<10 yrs	75(76.5)	14(82.4)	.759
>= 10 yrs	23(23.5)	3(17.6)	
Number of days of alcohol use per week			
<=4 days	10(10.2)	3(17.6)	.405
5-7 days	88(89.8)	14(82.4)	
Amount of alcohol use per day			
<1/2 liter	65(66.3)	9(52.9)	.287
>=1/2 liter	33(33.7)	8(47.1)	
Any previous de-addiction given			
yes	10(10.22)	0(0.0)	.354
no	88(89.8)	17(100)	
If yes, the number of times the treatment given			
once	5(50)		
twice	3(30)		
thrice	2(20)		
Legal problems			
Present	6(6.1)	2(11.8)	.336
Absent	92(93.9)	15(88.2)	
Financial problems			.072
Present	23(23.5)	8(47.1)	
Absent	75(76.5)	9(52.9)	
Any recent adverse life			

event			
Present	10(10.2)	2(11.8)	>.999
Absent	88(89.8)	15(88.2)	
SADD Score			
10 – 19 (medium dependence)	15(15.3)	2(11.8)	>.999
>= 20 (high dependence)	83(84.7)	15(88.2)	
CIWA –ar			
<10	64(65.3)	13(76.5)	.366
>= 10	34(34.7)	4(23.5)	
Rotter's total score			
12-23 (external locus of control)	58(59.2)	12(70.6)	.374

There was no significant difference between the profiles of the subjects who were lost to follow up and the 98 subjects who completed the study.

CHAPTER VI

Discussion

6.1 Socio-demographic variables of 98 participants who followed up after the 3 months follow up period

Age: The mean age was 37.17 years and the standard deviation was 9.86 years. The age ranged from 19 years to 66 years.

The statistical analysis of age distribution of Indian population from the year 2004 to 2014 showed that 65.9 % population fell in the age group of 15 – 64 years of age, 28.75 % fell in the age group of 0-14 years and 5.36 % fell in the age group of 65 years or more(70). This shows that the population in the study is similar to the Indian population in terms of age distribution.

Gender distribution of the sample: Out of the total 115 participants recruited in the study only 1 participant was a female.

According to a National Household Survey (2000-2001), the prevalence of alcohol dependence in males in India was found to be 21 % and in females was found to be less than5 %. However, there is a lack of knowledge about women alcoholism in India(71). Women alcoholism is invariably associated with high rates of psychiatric disorders and traumatic early life events. Studies have shown that odds ratio to develop alcohol abuse in women with depression was 4.1 as compared to 2.67 in men. A national survey has shown several psychological problems in women with

alcohol use ranging from anxiety, depression, insomnia, guilt feeling to suicide attempts(72).

In a study done in rural parts of North India it was found that the relative risk of alcohol use in men when compared to women was found to be 3.64(73).

A study done in the rural population from West Bengal showed that 19 % men and 2.4 % women were current users of alcohol(74).

There is a gap between women alcoholism and treatment seeking behavior in women for alcohol use disorder. Possible reasons include the stigma associated with alcohol use in women in India as well as the stigma associated with help seeking for substance abuse. Studies have shown that women have increased “proneness to shame”, which results in increased perceived self-stigma. The societal as well as the perceived self-stigma act as a major hindrance in treatment seeking behavior in women alcohol users in India(75).

This could explain the low female proportion in the sample.

Educational status of participants: Nearly half of the participants (50 %) have higher primary school education and only 2% have professional education.

Studies in the West have shown school drop outs have 6.34 times more chance of developing alcohol dependence when compared to degree holders. The relative risk of developing alcohol dependence is 3.01 in college drop outs when compared to those who completed college(76).

Excessive alcohol drinking was found in individuals with low educational qualifications. Alcohol related problems were high in the lower educational group. Psychological dependence was more in the intermediate educational group(77).

Low educational attainment was found to be an independent risk factor for alcohol use in the Hungarian population(51).

A study in Chinese population has shown lower rate of alcohol use in higher educational group when compared to lower educational group(78).

Studies in India have shown that people with lower education level, belonging to lower socio-economic status, unemployed, unskilled, semiskilled, skilled occupational group were associated with alcohol use disorders(79).

Indian studies have shown higher rates of alcohol consumption of about 39 % in individuals with less educational qualification when compared to 28 % in individuals with higher educational qualification(80).

The current study supports the consensus that alcohol use disorder is more common in individuals with lower educational achievement.

Marital status: The married participants were 75.5 %. 4.1 % participants were separated from their spouse.

Marriage is considered as a protective factor for substance abuse including alcohol use disorders. Studies have shown that having a close relationship with spouse

results in favorable outcome in people seeking treatment for alcohol use disorders. Marriage offers a social support significant enough for treatment retention, relapse prevention and subjective wellbeing(81).

There are studies which have quoted a high risk of alcohol use in married men. A study done in rural area of North India showed a relative risk of using alcohol as high as 2.51 in married men when compared to single men(73).

Community studies in India have shown that men are reluctant to seek treatment for alcohol use disorder due reasons of stigma and disbelief in the treating system. It is the immediate family members and wife who assist these men in treatment seeking(82).

Thus it is very clear that participants who have social support and are married are more likely to seek treatment when compared to single or separated individuals. This study also supports the above hypothesis and substantiates the belief that married individuals have higher treatment seeking rates.

Occupation: Majority of the participants (55.1 %) were manual laborers and held unskilled employment. Only one participant was professionally employed.

In a Western study farm workers were found to be more prone to abuse alcohol when compared to other occupational classes(83).

A study done on commercial vehicle drivers of Nigeria found that hazardous alcohol use was higher in individuals with stressful job conditions, long duration of job

hours, lack of supervision at work place with easy availability of alcohol in the vicinity(51).

A community based study in the South Indian population had shown that manual laborer as an occupational status was an independent risk factor for alcohol use with an odds ratio of 2.08(84).

An Indian study done in the rural parts of North India have shown increased alcohol abuse among the farming population with a relative risk of 1.43 in the male farmers and 1.80 in the female farmers(73).

An Indian study focusing on IT professionals found that among the software engineers who had increased job stress and depression, had 4.1 increased prevalence of alcohol harmful use when compared to software engineers who were non-depressed(85).

In the Indian population, majority alcohol users belong to the unskilled, semi-skilled, skilled and unemployed occupation group(79).

The present study support the above findings as majority of the participants are manual laborers.

Type of family: 54.1 % of the participants belonged to nuclear family and 41.8 % belonged to extended family.

Studies done in West have shown clear relationship between family structure and substance abuse pattern. Single parent families and nuclear families report high levels of substance abuse including alcohol abuse. Extended family type, better communication pattern between family members and family norms prohibiting alcohol use were found to be a protective factor(54).

Indian studies have shown that nuclear families are at increased risk for alcohol abuse and problems related to alcoholism, when compared to joint families(86).

A few Indian studies have shown a higher risk of alcohol use in both nuclear and joint families(73).

This study supports the findings of nuclear families being at increased risk for alcohol abuse when compared to other family structures.

Type of residence: In the present study alcohol use was found to be more prevalent in the rural population, 58.2 % of the sample.

Cross sectional studies in Kenya had shown lower rate of alcohol use in rural and low socio-economic areas of the country(87).

Studies in the West have shown that individuals living in urban area report more alcohol use when compared to rural inhabitants, even though the lifetime risk of alcohol use may be same in both the group(88).

Some studies from West have shown a higher rate of alcohol use disorder in the urban population when compared to rural population. A few studies have shown equivalent rates of alcohol use disorder in both the geographical population(88).

A South Indian study had shown that rural area of residence was significantly associated with hazardous alcohol use with an odds ratio of 2.82(89).

In studies done in various states of north India, prevalence of alcoholism was found to be more in the rural and urban slum population when compared to the urban population(90).

With increase in urbanization, alcohol hazardous use has been increasing in India. The prevalence of alcohol abuse is high among the urban slum dwellers(3).

The community based surveys have shown that the social, financial and health related problems are more common in the urban slums when compared to the rural population(90).

The present study finds alcohol abuse to be more common among the rural population when compared to the urban population. Although Vellore is now classified as a city, the catchment area served by the hospital is largely rural and the findings may be a reflection of this.

Socio-economic Status: 51 % of the sample belongs to lower socio-economic status.

Studies in the west have shown a higher rate of alcohol dependence in individuals belonging to lower socio economic group and higher rate of alcohol abuse in individuals belonging to upper socio economic group(91).

A study in Chinese population have shown lower rate of alcohol use in lower income groups compared to higher income group(78).

The previous Indian studies have shown as high as 46 % prevalence of alcohol abuse among individuals belonging to lower socio-economic status, when compared to 31 % prevalence in higher and middle socio-economic status people(80).

The current study highlights the fact that individuals belonging to lower socio-economic statuses are at a high risk for alcohol abuse. This finding is in consensus with findings from previous Western as well as Indian studies.

Religion: 91.8 % participants were Hindus and the remaining were Christians. Religiosity is a protective factor in alcoholism. Religion is found to have a high protective value for alcohol use among the Buddhist in Thailand (51).

Studies from the West have shown higher alcohol use rates in the Catholics and higher abstinence rates in the Protestants(92).

In a Mauritian study high rates of abstainers were found among the Muslims. Religious commitment and abstention norm were found to be highly associated with abstinence(93).

In a study done in the rural areas of Ajmer district, Rajasthan showed more prevalence of alcohol use among Hindu males(73)**.**

Islamic religion was found to be protective factor in a study done in south Indian population(84).

In a study done in rural South India, it was found that the prevalence of alcohol use was high among the Christians (56%), followed by Hindus (25 %), with lowest prevalence in the Muslims (8%)(80).

Since the sample did not contain a representative distribution of religions, it would not be possible to comment on the association as a risk factor.

Adequate family support: In the present study 95.9 % (n=94) participants had adequate family support and 4.1 % (n= 4) participants did not have an adequate family support.

Studies have shown that there is high rate of hazardous drinking pattern in individuals with poor primary support system(94).

Studies in the West have shown that post treatment outcome and recovery is affected by the support system available to the individual. Larger number of people involved in individual care and availability of more supportive relationships are related to greater rate of abstinence(55).

Indian families function on the basis of inter-dependence and almost all the family members are involved in the care of the individual. Studies from India have shown that the larger the size of family, the more easily the individual is integrated in the family with more favorable outcome. The concept of larger extended families is more prevalent in the rural India(95).

Individuals who remit with the help of family members have good long term remission rate compared to individuals who remit without the help of family members. Individuals with poor support system have avoidance as the main coping mechanism, which is a poor predictor for remission(20).

In the present study most of the participants felt they had adequate family support. Since the centre is a private paying facility, it is possible that those with poor family support would not have sought treatment here, and were therefore underrepresented in the sample.

6.2 Family history of alcohol use in individuals with alcohol use disorder

In this study, 75 participants have family history of alcohol use. Participants with first degree relatives using alcohol are 89.3 %, with second degree relatives are 8 % and with third degree relative are 2.7 %.

Studies have shown an increase in the risk of alcoholism in relatives of alcohol dependence patients by three to five times. An early age of onset of alcohol use and

early age of dependence pattern is seen in patients with first degree relative having alcohol abuse or dependence syndrome(96).

In various studies in the West, it was found that a positive history of alcohol use in the family was related to increased severity of alcohol dependence. An onset of alcohol use before 25 years of age was found to be strongly associated with alcohol use disorder in the first degree relatives. However, there are not much Indian studies focusing on this association(96).

The finding in this study supports the consensus about the increased risk of alcohol use disorders in individuals with first degree relatives using alcohol.

6.2 Abstinence status at three months follow-up:

This study found that 30.6% of participants were completely abstinent after 3 months.

A cohort study assessing the outcome at 3, 6, 12 and 24 months after an intensive therapy for alcohol dependence, showed abstinence or decrease in drinking in 53 % patients at the end of 3 months, 44.3 % at the end of 6 months, 30.6 % at the end of 12 months, 25.7 % at the end of 24 months(41).

In a cohort study in Japanese subjects receiving treatment, the abstinence rate in a follow up period of 1 – 3 years was found to be 7 – 30 %(42).

In a meta-analysis the 3 year remission rate was found to be 21 % in untreated individuals and 43 % in treated individuals(20).

Few studies suggest an outcome of 6-18 % abstinence at a two year follow up. However, studies based on self-report has stated an abstinence rate of 30 % at 2-3 year follow up period(37).

Studies focusing on outpatient long term intensive therapy for alcoholics (OLITA) has found an abstinence rate as high as 50 % in a nine year follow up period(37).

In a 2 year follow up study of 146 patients in India it was found that 33.16 % patients had relapse, 35.49 % had partial improvement and 31.35 % had complete abstinence(97).

In the Indian follow up studies maximum attrition was found during 3 – 6 months of follow up period. A study including in-patients showed an abstinent rate of 46 %(1).

The abstinence rate in this study was found to be similar to the previous Western as well as Indian studies.

6.3 Factors associated with complete abstinence:

Family history of alcohol use

Degree of relatedness of family member, using alcohol, to the participant:

In this study we found that abstinence rate was higher among individuals who had a family history of alcohol use in the third degree relatives, when compared to individuals who had a family history of alcohol use in the first degree relatives.

In a Western study it was found that the risk of alcohol dependence increases by 45 % in individuals with family history of alcoholism in second and third degree relative when compared to 86 % increased risk in individuals with family history of alcoholism in first degree relatives(98).

Individuals with immediate first degree relatives like parents, siblings using alcohol are more likely to have hazardous alcohol use pattern(51).

Studies in the West have shown that individuals with positive family history of alcohol use disorder have a neuro-developmental lag in the brain maturation and neural connectivity pattern which is responsible for increased risk of alcohol use disorders in these individuals(99).

Twin and adoption studies have shown 50-60 % genetic influence associated with risk variance of alcoholism(100).

Studies in the west have shown that early age of onset of alcohol use, progression to dependence pattern, amount of alcohol consumed and prediction of outcome are genetically mediated(101).

Adoption studies have shown that the patterns of alcoholism are more strongly associated with the biological parents than the adoptees. Twin studies have shown that 45-65 % variability in alcoholism is accounted by genetic factors(102).

Studies have shown that family history of alcohol use is a poor prognostic factor in terms of treatment outcome(103).

This study also supports the consensus that family history of alcohol use is a risk factor for individual alcohol use disorder. The degree of relatedness is also significant and first degree relatedness is a poor indicator of abstinence, when compared to second or third degree relatedness.

Alcohol use history

SADD score:

In this study it was found that participants with a SADD score equal to medium dependence had more abstinence rate, when compared to individuals with a score equal to high dependence.

Previous studies have shown that higher severity of alcohol use, greater number of years of heavy alcohol use, greater number of prior treatments and early age of onset of alcohol use is related to poor outcome(104).

Studies have shown that baseline alcohol use and dependence severity are important predictors for outcome(105).

This study supports the finding from the previous studies. Individuals with high levels of dependence have lower abstinence rate when compared to individuals with low levels of dependence.

Treatment related variables:

Type of treatment received:

This study has found that participants, who received both pharmacological and non-pharmacological treatment, had higher rates of abstinence when compared to patients who received only pharmacological or non-pharmacological treatment.

It is known that a combined pharmacological treatment and non-pharmacological approach has a better outcome(34).

Medication addresses the neurobiological basis of alcohol use disorder and psychological interventions focuses on the habits and behaviors related to substance abuse(17).

Non-pharmacological methods promote a better working alliance between the patient and the therapist which leads to better medication adherence resulting in a favorable outcome(24).

This study endorses this finding.

Deterrent therapy:

This study shows that participants, who received Disulfiram as deterrent therapy, had higher rates of abstinence when compared to participants who did not receive Disulfiram.

Studies have shown that Disulfiram has benefits in short term abstinence. It has more days of abstinence until relapse and lessens the number of drinking days(106).

There is modest evidence to suggest that supervised Disulfiram decreases the drinking frequency and increases the abstinence rate. However, evidence to suggest complete long term abstinence is lacking(107).

Studies have shown that Disulfiram offers a better treatment retention and higher rates of longer duration abstinence(108).

Duration of abstinence as long as 24 weeks have been achieved by strict adherence to Disulfiram (109).

An Indian study showed 54 % participants were abstinent on Disulfiram for a 6 month follow up period(110).

We conclude from the study that Disulfiram helps in maintenance of abstinence for atleast a minimum of 3 months

Regular adherence on medications:

In this study, it was found that the participants who were regularly adherent on medications, had higher rates of abstinence when compared to participants who were not regular on medication. Subjects who are adherent to medication have a better outcome, when compared to non-adherent groups.

In a previous study, treatment outcome with naltrexone was studied and it was found that non-adherent subjects had a relapse rate of 50 % when compared to 14 % in the adherent subjects(24).

Researches in the past have shown "pill adherence "to be related to better outcome. It has been seen that the subjects had better outcome if they had 80 % adherence to medications prescribed(24).

A combination of good medication adherence and regular behavioral therapy sessions to improve adherence, helps in better treatment outcome(24).

The present study supports this finding.

Regular follow-up visits

The present study has shown that participants who were regularly coming for follow up had higher rates of abstinence when compared to patients who were not regular for follow up.

In the multivariate analysis ($p<0.05$), the only factor found to be associated with complete abstinence was regular follow-up visits to the hospital. Regular contact with the treating staff is one of the important factors leading to positive outcome.

Studies in the West have also shown that continued care in the form of regular follow up visits have a better long term outcome as it helps better crisis management and prevents a relapse(111).

Studies have shown regular adherence to treatment and regular follow up is associated with better therapeutic alliance between the patient and the therapist, which leads to better outcome(112).

An Indian study have shown that regular follow up with the relatives to the out-patient department is associated with higher rates of abstinence(64).

Studies in India have shown that subjects who are on regular follow up have longer duration for relapse(65).

In a community study in India, it was found that continued after care in the form of regular follow up visits with the counselor, ongoing contact with the therapist and supported employment were factors related to better long term recovery rate(48).

This study supports the consensus that regular follow up visit with the treating team helps maintain longer duration abstinence. Regularity in contact may be influenced by multiple factors.

6.4 Limitations:

1. This study was conducted in a tertiary care set up, hence generalization of the study results to all clinical settings are not possible.
2. Only 5 out of the total 98 subjects, who followed up after 3months follow up, were interviewed in person. The remaining 93 subjects were interviewed over the telephone. The information collected over phone was cross checked with the medical record of the patient and also corroborated with the primary care giver over the telephone.
3. Follow up period was limited to 3 months.
4. Different care givers accompanied some of the participants in the follow up visit. The same was true of the telephonic follow up. Getting information from the same person could have improved the reliability of information.
5. Information about the interim visits and details of status were limited to what was entered in the medical record of the participant.

Strengths:

1. The prospective cohort design is best suited to a study of factors affecting outcome.
2. The sample size exceeded the minimum required number for statistical validity of the analysis.
3. Dropout rate was low, and the two groups (dropouts and completers) did not differ in their baseline profile.
4. The study sample population is similar in terms of socio-demographic profile of earlier Indian studies and hence the results can be compared to existing literature.
5. Since all patients received treatment as usual, the findings are generalizable clinically.

Conclusion

1. The proportion of participants who remained completely abstinent at the end of 3 month period of standard treatment in a cohort of newly enrolled alcohol dependent subjects of a tertiary care psychiatric unit of a general hospital was 30.6 %.
2. Factors associated with abstinence included regularity with follow up visits in hospital, good adherence to medication, use of Disulfiram, receiving combination of medication and psychological management, a less severe form of dependence, and family history of alcohol use in second or third degree relatives rather than first degree relatives.
3. In multivariate analysis, the factor associated with complete abstinence for 3 month follow up period was regular follow up visits to the hospital. Hence, focus on engaging the patient and family in treatment, and ensuring regular visits, may be crucial to a better outcome in alcohol dependence. This would mandate the use of combination of pharmacological and non-pharmacological strategies.
4. Telephonic follow up in India is acceptable and possible, and may be used to improve data collection in future prospective studies.

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APPENDIX

1. Information sheet in English.
2. Information sheet in Tamil.
3. Proforma for collecting data – 1st and 2nd assessment.
4. Alcohol Dependence Data Questionnaire (SADD).
5. Clinical Institute withdrawal Assessment of Alcohol – scale revised (CIWA-Ar).
6. Rotter's scale for assessing locus of control.

APPENDIX I

INFORMATION SHEET

TITLE OF STUDY

Study of factors affecting outcomes in people with alcohol dependence syndrome.

INSTITUTION: Christian Medical College , Vellore

NATURE AND PURPOSE OF STUDY: My name is Dr. Preeti Mathew. I am doing higher studies here. I am interested in knowing more about how best to help people suffering from alcohol addiction. So I want to get information from you, both about your condition, and to see how much our treatment helps you.

We will use this information to understand which part of our treatment helps you the most and how we can improve our treatment. It will also help me complete my higher studies.

Taking part in this study will not change your treatment in any way. There will be no change in the treatment if you do not wish to take part in it.

PROCEDURE TO BE FOLLOWED:

I will ask you some questions in your mother tongue. These questions will be very similar to the ones that the doctor has already asked you and will all relate to understanding your problem.

I will also collect information from your relative.

I will give you an appointment to meet again in three months.

With your permission, I will retain your phone number to contact you to remind you of the appointment, one week before the due date.

If you are not able to come on that date, we can fix an alternate date, or you could help me by answering questions over the telephone.

EXPECTED DURATION OF INVOLVEMENT:

The assessment will be done in two sessions about 3 months apart. Each session will last for approximately half an hour.

POSSIBLE BENEFITS OF THE STUDY:

The information which we get from you will help us in knowing which part of our treatment is the best. This will help us to improve our treatment methods. There is no extra benefit for you or change in treatment because of the study. We hope that future patients will benefit from the findings of this study.

CONFIDENTIALITY:

The records and details obtained in this study will always be kept confidential. It will only be available to doctors conducting the study. Your personal details will only be used for research purpose. You will never be referred by name or identified in any report or publication.

RIGHT TO WITHDRAW FROM THE STUDY:

You are free to leave the study at any time.Your decision to withdraw from the study will not affect your treatment in this hospital. In case of any doubt or question contact me at Psychiatry unit 2 office, phone number 0416-228-4520

My email ID is preeti_mathew08@yahoo.co.in

தகவல் மற்றும் ஒப்புதல் படிவம்

ஆய்வில் கலந்துகொள்ளும் அன்பரே!

நான் ஒரு மருத்துவ பட்ட மேற்படிப்பு மாணவர். இது எனது பட்ட மேற்படிப்பிற்காக நடத்தப்படும் ஆய்வு.

மதுப்பழக்கம் உள்ளவர்கள் மற்றும் மதுப்பழக்கத்திற்கு அடிமைப்பட்டவர்களிடத்திலிருந்து, திடீர்பழக்கத்தினால் ஏற்படும் பிரச்சனைகள் பற்றிய தகவல்களை, கேட்டறிவதே இந்த ஆய்வின் நோக்கமாகும். நீங்கள் அளிக்கும் இந்த தகவல்கள் மூலமாக தற்போது நாங்கள் அளிக்கும் சிகிச்சையில் உங்களுக்கு உதவி செய்யவும், மேலும் சிறந்த சிகிச்சை முறையை நாங்கள் கடைபிடிக்கவும் பயனுள்ளதாக இருக்கும்

தங்களின் அனுமதியுடன் உங்களுடைய தனிப்பட்ட அந்தரங்க விபரங்கள், திடீர்பழக்க முறை மற்றும் உடல்நலம் சம்மந்தப்ப விபரங்களை நான் சேகரிக்க உள்ளேன். உங்களுடைய தாய் மொழியிலேயே இந்த மதுப்பழக்கத்தினால் உங்களுக்கு ஏற்பட்டுள்ள கடுமையான பாதிப்புகள், இப்பழக்கத்திலிருந்து விடுபட முடியாத பிரச்சனைகள் மற்றும் இப்பழக்கத்தை மேற்கொள்ளுதல் போன்றவற்றைப் பற்றி நான் தங்களிட கேட்பேன். இத்தகவல்கள் உங்கள் உறவினர்களிடமும் கேட்கப்படும்.

சுமார் 3 மாதங்கள் வரை தங்கள் கைப்பேசி எண்கள், உங்களிடம் தொடர்புகொள்வதற்காக பயன்படுத்தப்படும். மூன்று மாதங்கள் முடிந்த பின்பு கைப்பேசி மூலம் உங்களையும், உங்களின் உறவினரையும் தொடர்பு கொள்ளவோம்.

உங்கள் பெயர், விலாசம் மற்றும் தனிப்பட்ட அந்தரங்க விபரங்கள் வேறு யாருக்கும் கண்டிப்பாக அறிவிக்கப்படமாட்டாது.

இந்த ஆய்வில் நீங்கள் கலந்துகொண்டாலும், கலந்துகொள்ளாமல் போனாலும் ஏற்கனவே உங்களுக்கு மருத்துவமனையில் அளிக்கப்படும் சிகிச்சை எந்தவிதத்திலும் பாதிக்கப்படமாட்டாது. மேலும், இந்த ஆய்வில் நீங்கள் உங்களின் சொந்த விருப்பப்படி கலந்துகொள்ளவும், விலகிக்கொள்ளவும் முழு சுதந்திரம் உள்ளது.

இந்த ஆய்வைக்குறித்த உங்கள் சந்தேகங்கள், மற்றும் விபரங்களை அறிந்துகொள்ள தொடர்புகொள்ள வேண்டிய முகவரி :

மனநல மருத்துவமனை – பிரிவு 2,
சி. எம். சி.
பாகாயம்,
வேலூர் – 632 002
தொலைபேசி : 0416 – 2284520

நன்றி,

டாக்டர் ப்ரீத்தி மாதீயூ
ஆய்வாளர்.

ஒப்புதல் அளிப்பவர் கையொப்பம்:

CONSENT FORM IN TAMIL

ஒப்புதல் படிவம்

ஆய்வில் பங்கேற்பதற்கான ஒப்புதல்:

ஆய்வின் தலைப்பு:

குடிநோயினால் ஏற்படும் விளைவுகளுக்காக மனநல மையத்திற்கு வரும் நபர்களுக்கு - மூன்று மாதம் தொடர்ந்து மது தவிர்ப்புதல் - ஒரு ஆய்வு

ஆய்வு எண்: _____

கலந்து கொள்பவரின் முதற்பெயர்: _____ கலந்து கொள்பவரின் பெயர்: _____

பிறந்து நாள் / வயது: _____

(கலந்து கொள்பவர்)

i). நான் உறுதி செய்வது என்வென்றால் _____தேதியின் நடக்கக இருக்கம் ஆய்வு குறித்து தகவல் தாளை முழமையாக படித்து புரிந்து கொண்டேன். இதைப்பற்றி கேள்வி கேட்கவும் வாய்ப்பு கிடைத்தது.

ii). நான் புரிந்து கொண்டது என்னவென்றால், நானாக முன்வந்து இந்த ஆய்வில் கலந்து கொள்கிறேன் என்றும், நான் எப்பொழுது வேண்டுமானாலும், காரணம் இன்றி இந்த ஆய்வில் இருந்து விலக்கிக்கொள்ளலாம் என்றும் இதனால், என்னுடைய வைத்தியமோ சட்ட உரிமையோ பாதிக்கப்படாது என்பதை அறிவேன்.

iii). நான் புரிந்து கொண்டது என்னவென்றால் மருத்துவ பரிசோதனைக்கு பண உதவு செய்பவர்கள் அல்லது அவர்கு பதிலாக பண உதவு செய்பவர்கள் நன்னடத்தை குழு, கட்டுப்பாட்டு அதிகாரிகள் ஆகியோருக்கு என்னுடைய உடல்நலம், மனநலம் பற்றிய மருத்துவக் குறிப்புகளைப் பார்ப்பதற்கு என்னுடைய அனுமதி தேவையில்லை என்பதும் நான் ஆய்வில் இருந்து விலகிக்கொண்டாலும் இப்பொழுதோ அல்லது எதிர்காலத்திலோ, என்னுடைய அனுமதி தேவையில்லை என்பதை அறிவேன். என்னுடைய மருத்துவக் குறிப்புகளைப் பார்ப்பதற்கு ஒத்துக்கொள்கிறேன். என்னுடைய பெய மற்றும் முகவரி மூன்றாவது மனிதர்களுக்கு தெரியப்படுத்தப்படமாட்டாது என்பதை அறிவேன்

iv). இந்த ஆய்வில் மூலம் தெரிவரும் முடிவுகள் அறிவியல் நோக்கத்திற்காக பயன்படுத்தப்படுவதை நான் ஒத்துக்கொள்கிறேன்.

v). நான் இந்த ஆய்வில் ஒத்துக்கொள்ள சம்மதிக்கிறேன்

பங்குகொள்பவரின் கையெப்பம்: _____

தேதி:

பங்குகொள்பவரின் பெயர்: _____

பிரதிநிதி: _____

தேதி: _____

பெயர்: _____

ஆய்வாளரின் கையொப்பம்:

தேதி:

ஆய்வாளரின் பெயர்: _____

தேதி: _____

சாட்சியின் பெயர்: _____

மற்றும் முகவரி : _____

APPENDIX III

INTIAL ASSESSMENT PROFORMA :-

A.SOCIO-DEMOGRAPHIC FACTORS

1.AGE

2.SEX

3.MARITAL STATUS

Married

Single

Separated

Widow/widower

4. TYPE OF FAMILY

NUCLEAR

JOINT

EXTENDED

5. EDUCATION

No formal education

Primary schooling

Higher primary

High school (10 th)

Intermediate schooling (12 th)

College (UG/PG)

Professional course

6.OCCUPATION

Unemployed

Unskilled

Semiskilled

Skilled

Semiprofessional

Professional

7.Economic status

Upper class

Upper middle class

Middle class

Lower class

8. Religion

Hindu

Muslim

Christian

Others

9. TYPE OF AREA OF RESIDENCE

Urban

Rural

SECOND ASSESSMENT OF THE PARTICIPANTS AFTER 3 MONTHS :

1. **ABSTINENT STATUS AT FOLLOW UP**
   Complete
   Incomplete

2. **ANY LAPSES/ RELAPSES**

   Yes

   No

3. **HOW MANY NUMBERS OF LAPSES / RELAPSES –**

4. **NUMBER OF COMPLETE ABSTINENT DAYS SINCE INDEX VISIT TO LAPSE/RELAPSE**

5. **WAS PATIENT COMING FOR REGULAR FOLLOW-UP**

6. **DID PATIENT CONTINUE TREATMENT IN THIS HOSPITAL AFTER LAPSE/RELAPSE**

7. **TYPE OF TREATMENT GIVEN**

   In-patient
   Out patient

8. **DID PATIENT REQUIRE EMERGENCY CARE ROOM TREATMENT**

9. WHAT TYPE OF TREATMENT RECEIVED

Pharmacological
Non-pharmacological
Both

10. DID PATIENT ATTEND ANY GROUP,(if yes which group)

AA group
Alcohol group in MHC
Occupation therapy in MHC

11. DID PATIENT RECEIVE DISULFIRAM

YES
NO

12.ANY OTHER ANTCRAVING AGENT RECEIVED BY THE PATIENT

Yes
No

13. ANY OTHER ALTERNATIVE TREATMENT TAKEN

Yes
No

14. WAS PATIENT REGULAR ON MEDICATION

Yes
No

15. DOES THE WIFE / PRIMARY CARE GIVER CORRABORATE THE HISTORY ABOUT ABSTINENCE

Yes
No

APPENDIX IV

SADD - Short Alcohol Dependence Data Questionnaire

INSTRUCTIONS: The following questions cover a wide range of topics to do with drinking. Please read each question carefully but do not think too much about its exact meaning. Think about your MOST RECENT drinking habits and answer each question by circling the MOST APPROPRIATE heading. If you have any difficulties ASK FOR HELP.

	Never	Sometimes	Often	Nearly Always
1 . Do you find difficulty in getting the thought of drinking out of your mind?	0	1	2	3
2. Is getting drunk more important than your next meal?	0	1	2	3
3. Do you plan your day around when and where you can drink?	0	1	2	3
4. Do you drink in the morning, afternoon and evening?	0	1	2	3
5. Do you drink for the effect of alcohol without caring what the drink is?	0	1	2	3
6. Do you drink as much as you want irrespective of what you are doing the next day?	0	1	2	3
7. Given that many problems might be caused by alcohol do you still drink too much?	0	1	2	3
8. Do you know that you won't be able to	0	1	2	3

APPENDIX V

Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-Ar)

Patient:_____ **Date:** _____ **Time:** _____ (24 hour clock, midnight = 00:00)

Pulse or heart rate, taken for one minute:_____ **Blood pressure:**_____

NAUSEA AND VOMITING -- Ask "Do you feel sick to your stomach? Have you vomited?" Observation.
0 no nausea and no vomiting
1 mild nausea with no vomiting
2
3
4 intermittent nausea with dry heaves
5
6
7 constant nausea, frequent dry heaves and vomiting

TACTILE DISTURBANCES -- Ask "Have you any itching, pins and needles sensations, any burning, any numbness, or do you feel bugs crawling on or under your skin?" Observation.
0 none
1 very mild itching, pins and needles, burning or numbness
2 mild itching, pins and needles, burning or numbness
3 moderate itching, pins and needles, burning or numbness
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

TREMOR -- Arms extended and fingers spread apart. Observation.
0 no tremor
1 not visible, but can be felt fingertip to fingertip
2
3
4 moderate, with patient's arms extended
5
6
7 severe, even with arms not extended

AUDITORY DISTURBANCES -- Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" Observation.
0 not present
1 very mild harshness or ability to frighten
2 mild harshness or ability to frighten
3 moderate harshness or ability to frighten
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

PAROXYSMAL SWEATS -- Observation.
0 no sweat visible
1 barely perceptible sweating, palms moist
2
3
4 beads of sweat obvious on forehead
5
6
7 drenching sweats

VISUAL DISTURBANCES -- Ask "Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" Observation.
0 not present
1 very mild sensitivity
2 mild sensitivity
3 moderate sensitivity
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

ANXIETY -- Ask "Do you feel nervous?" Observation.
0 no anxiety, at ease
1 mild anxious
2
3
4 moderately anxious, or guarded, so anxiety is inferred
5
6
7 equivalent to acute panic states as seen in severe delirium or acute schizophrenic reactions

HEADACHE, FULLNESS IN HEAD -- Ask "Does your head feel different? Does it feel like there is a band around your head?" Do not rate for dizziness or lightheadedness. Otherwise, rate severity.
0 not present
1 very mild
2 mild
3 moderate
4 moderately severe
5 severe
6 very severe
7 extremely severe

APPENDIX VI

Rotter's Locus of Control Scale

For each question select the statement that you agree with the most

1. a. Children get into trouble because their parents punish them too much.

   b. The trouble with most children nowadays is that their parents are too easy with them.

2. a. Many of the unhappy things in people's lives are partly due to bad luck.

   b. People's misfortunes result from the mistakes they make.

3. a. One of the major reasons why we have wars is because people don't take enough interest in politics.

   b. There will always be wars, no matter how hard people try to prevent them.

4. a. In the long run people get the respect they deserve in this world.

   b. Unfortunately, an individual's worth often passes unrecognized no matter how hard he tries.

5. a. The idea that teachers are unfair to students is nonsense.

   b. Most students don't realize the extent to which their grades are influenced by accidental happenings.

6. a. Without the right breaks one cannot be an effective leader.

   b. Capable people who fail to become leaders hive not taken advantage of their opportunities.

7. a. No matter how hard you try some people just don't like you.

   b. People who can't get others to like them don't understand how to get along with others.

8. a. Heredity plays the major role in determining one's personality.

   b. It is one's experiences in life which determine what they're like.

9. a. I have often found that what is going to happen will happen.

   b. Trusting to fate has never turned out as well for me as making a decision to take a definite course of action.

10. a. In the case of the well prepared student there is rarely if ever such a thing as an unfair test.

    b. Many times exam questions tend to be so unrelated to course work that studying in really useless.